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medical devices

Labeling

Regulatory Requirements for Medical Devices

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FDA 83-8216	Medical Device Listing - Information and Instructions (PB 84-154319, $8.50).

(Continued on inside back cover)

HHS Publication FDA 86-4203

Labeling

Regulatory Requirements for Medical Devices

Prepared by
Division of Small Manufacturers Assistance
Office of Training and Assistance

February 1986

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health
Rockville, Maryland 20857

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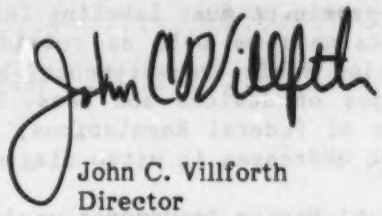
FOREWORD

In October 1982, the Food and Drug Administration established the Center for Devices and Radiological Health (CDRH) by merging the Bureau of Medical Devices and the Bureau of Radiological Health.

The Center develops and implements national programs to protect the public health in the fields of medical devices and radiological health. These programs are intended to assure the safety, effectiveness and proper labeling of medical devices, to control unnecessary human exposure to potentially hazardous ionizing and nonionizing radiation, and to ensure the safe, efficacious use of such radiation.

The Center publishes the results of its work in scientific journals and in its own technical reports. These reports provide a mechanism for disseminating results of CDRH and contractor projects. They are sold by the Government Printing Office and/or the National Technical Information Service.

We welcome your comments and requests for further information.



John C. Villforth
Director
Center for Devices and
Radiological Health

PREFACE

This booklet explains label and labeling regulations and requirements for medical devices. The Food and Drug Administration has many labeling-related requirements to help assure that devices are used safely and effectively, including, but not limited to provisions on Misbranding in Section 502 of the Food, Drug, and Cosmetic Act. This publication explains such areas as advertising matter as labeling, what is false and misleading labeling, how prominent must labeling information be, what information must appear on containers as well as outside labels, adequate directions for use, prescription device requirements, and special labeling for particular devices or types of devices and uses. Reprints are included of Part 801, Title 21, Code of Federal Regulations, general labeling requirements, and Part 807, which addresses in vitro diagnostic products.

The Medical Device Amendments mandated the establishment of . . . "an identifiable office to provide technical and other non-financial assistance to small manufacturers of medical devices to assist them in complying with the requirements of the Federal Food, Drug, and Cosmetic Act." The Division of Small Manufacturers Assistance (DSMA) was established to meet these requirements. In addition to providing individual guidance and workshops, DSMA distributes a wide variety of printed materials, such as regulations, guidelines, policy statements, question-and-answer booklets, and other FDA documents that help manufacturers understand the substance and impact of requirements, as well as the simplest or most effective ways to meet them. This publication provides explanations and examples of ways that companies can readily comply with labeling requirements. The basic materials provided by this booklet should help you to get oriented and to focus on further specific questions you wish to ask. Feel free to visit, write, or call DSMA toll free at (800) 638-2041. The local D.C. area phone number is (301) 443-6597.

Joseph S. Arcarese
Director
Office of Training and Assistance

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ABSTRACT

Prepared by the Division of Small Manufacturers Assistance, Office of Training and Assistance, Center for Devices and Radiological Health. Labeling - Regulatory Requirements for Medical Devices. HHS Publication FDA 86-4203 (February 1986) (pp. 44).

This publication covers labeling requirements that all manufacturers must consider when a product requires a device labeling that must also bear adequate instructions for use, operating and servicing instructions, and such adequate warnings against uses that may be dangerous to health or information that may be necessary for the protection of users.

LABELING

INTRODUCTORY OUTLINE

Labels and labeling:

- The Food, Drug and Cosmetic Act makes use of, and distinguishes between, the terms "label" and "labeling."
- Certain provisions of Section 502 apply specifically to the "labeling" of a device; others are concerned with the "label" of a device. The terms are related, but not interchangeable.

Of the two, the term "label" has the narrower meaning. Generally, it consists of that part of the display confined to the device itself. "Labeling," on the other hand, deals not only with the label on the device, but also with all descriptive and informational matter that accompanies it.

Section 201(k) defines "label" as a:

- "display of written, printed, or graphic matter upon the immediate container of any article..." (The term "immediate container" does not include "package liners.")

Any word, statement or other information appearing on the immediate container must also appear "on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper."

Section 201 (m) defines "labeling" as:

- "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article" at any time while it is in interstate commerce, or while it is held for sale after shipment or delivery in interstate commerce.

The term "accompanied" is interpreted liberally to mean more than physical association with the product. It extends to posters, tags, pamphlets, circulars, booklets, direction sheets, fillers, etc. that may be displayed in proximity to the product.

Labeling and advertising:

- The distinction between labeling and advertising, both of which draw attention to the article to be sold, is often nebulous or superficial. Both are forms of publicity and they are used for an identical purpose.
- According to a recent appellate court decision: "Most, if not all, labeling is advertising. The term 'labeling' is defined in the Act as including all printed matter accompanying any article. Congress did not, and we cannot exclude from the definition printed matter which constitutes advertising."

Section 502(f)(1) and (2) requires that device labeling also bear:

- adequate directions for use
- operating and servicing instructions, and
- such adequate warnings against uses that may be dangerous to health or information that may be necessary for the protection of users.

All devices require directions for use, unless specifically exempted by regulation.

- See 21 CFR 801, Subpart D, for a list of conditions for exemption from this requirement.

Truth in labeling:

- In accordance with the Fair Packaging and Labeling Act (21 CFR Part 801), "truth in labeling" will be enforced for devices.

Labeling of sterile devices to provide information on expiration dates for guaranteed sterility:

- The FDA does not now require expiration dates for sterile devices except in those cases where it is necessary for safe and effective use of the device as intended by the labeling.

Misbranding

Section 502 of the Act contains provisions on misbranding. A drug or device is misbranded in the following instances:

- Its labeling is false or misleading.
- Its packaging does not bear a label containing the name of the place of business of the manufacturer, packer, or distributor and an accurate statement of the quantity of contents.
- Words, statements, or other required information are not prominently placed on the labeling or not clearly stated.
- Although it is intended for human use, its label fails to (a) bear the name and quantity or proportion of any narcotic or habitforming substance contained therein and (b) display the statement, "Warning: May Be Habitforming.
- Its label does not bear adequate directions for use; including warnings against use in certain pathological conditions; or by children where its use may be dangerous to health; or against unsafe dosage, or methods, or duration of administration or application.

- It is dangerous to health when used in the dosage or manner or with the frequency or duration prescribed, recommended or suggested in the labeling.

- It does not comply with the color additive provisions listed under Section 706 of the Act.

The Amendments provided new authority for dealing with misbranding of medical devices. These additional provisions state under what further circumstances a device is misbranded.

- The device's established name (if it has one), its name in an official compendium, or any common or usual name is not prominently printed in type at least half as large as that used for any proprietary name.

- The device is subject to a performance standard and it does not bear the labeling prescribed in that standard.

- There is a failure or refusal to comply with any requirement prescribed under Section 518 on notification and other remedies, failure to furnish material or information required under Section 518, or failure to furnish any materials or information requested by or under Section 519 on records and reports.

False or Misleading Labeling

Section 502(a) declares that a drug or device is misbranded if its labeling proves false or misleading in any particular.

- The expression "false or misleading" is not confined in meaning to untrue, forged, fraudulent, or deceptive. In fact, the word, statement or illustration may be true in the strict sense of the word and yet the labeling will be deemed actionable under the law, if it proves deceptive to the consumer.

- It is not a necessary condition that the labeling should

be flatly and baldly false; the word "misleading" in the Act means that labeling is deceptive if it is such as to create or lead to a false impression in the mind of the reader.

- A "false impression" may result not only from a false or deceptive statement, but may also be instilled in the mind of the purchaser by ambiguity and indirection. It may, as well, be caused by failure to inform the consumer of facts that are relevant to those statements actually made. In other words, the label that remains silent as to certain consequences may be as deceptive as the label that contains extravagant claims.

Examples of misleading labeling include:

- ambiguity, half-truths and trade puffery
- expressions of opinion or subjective statements
- failure to reveal material facts, consequences that may result from use, or the existence of difference of opinion

Objectionable labeling includes such practices as:

- deceptive pictorial matter
- misleading testimonials
- misleading list of parts or components
- brand or trade names instead of "established names " (See sections 201(h), 502(e)(2), and 508)

Examples of false representations are:

- incorrect, inadequate or incomplete identification
- unsubstantiated claims of therapeutic value

- o inaccuracies concerning condition, state, treatment, size, shape or style
- o substitution of parts or materials
- o subjective or unsubstantiated quality or performance claims
- o use of the prefix "U.S." or other similar indication suggesting government or agency approval or endorsement of the product

Adequate Directions for Use

21 CFR 801.5 defines "adequate directions for use" as:

- o "directions under which the layman can use a device safely and for the purpose for which it is intended." (See Section 801.4 for a definition of "intended use.")

Directions for use may be inadequate, among other reasons, because there is partial or total omission or incorrect specification of:

- o statements of all conditions, purposes or uses for which such device is intended, including conditions, purposes or uses for which it is prescribed, recommended or suggested in its oral, written, printed or graphic advertising, and conditions, purposes or uses for which the drug or device is commonly used (except that such statements shall not refer to conditions, uses, or purposes for which the drug or device can be safely used only under the supervision of a practitioner licensed by law and for which it is advertised solely to such practitioner)
- o quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions
- o frequency of administration or application
- o duration of administration or application
- o time of administration or application (in relation to

time of meals, time of onset of symptoms, or other time factors)

- o route or method of administration or application
- o preparation for use, adjustment of temperature, or other manipulation or process

Prescription Devices

21 CFR 801.109 provides exemption for prescription devices.

- o Certain devices--because of some potential for harmful effect, or the method of their use, or collateral measures necessary to their use -- are not safe except under the supervision of a practitioner licensed by law to direct their use. Hence, such devices for which "adequate directions for use" cannot be prepared shall be exempt from section 501(f)(1) of the Act provided that all conditions specified in the regulation are met.

These conditions require that the device be:

- o in the possession of a person or his agents or employees regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of prescription drugs, or
- o in the possession of a practitioner, such as physician, dentist, and veterinarian, licensed by law to use or order the use of such devices, and
- o sold only to or on the prescription or order of such practitioner for use in the course of his professional practice.

In addition, the label of the prescribed device (other than instruments) is required to bear:

- o the statement "Caution: Federal law restricts this

device to sale by or on the order of a _____," the blank to be filled with the word "physician," "dentist," "veterinarian," or with the descriptive designation of any other practioners licensed by the law of the State in which he practices to use or order the use of the device

- the recommended or usual dosage

- the method of its application or use

Labeling on or within the package from which the device is to be dispensed must also bear:

- information for use, including indications, effects, dosages, routes, methods, frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is advertised or represented.

Instructions for use of such devices:

- When a device is capable of producing serious injury unless handled by a person thoroughly familiar with its operation, such as an X-ray machine, the directions for use must indeed provide detailed information. The Food and Drug Administration, for example, has indicated the type of directions that should accompany X-ray apparatus.

Warnings against probable misuse:

- Directions for use must be supplemented, in the appropriate instance, with adequate warnings against the use of the drug or device under certain conditions. Such cautionary statement, similar to the directions statement, may appear in the labeling of such a product; it is not necessary that these be printed on the label. In each instance, the responsibility for the adequacy of the warning statement to appear on the labeling rests with the manufacturer or distributor.

Firms that have questions on labeling or wish to obtain CDRH comment or guidance may consult with the Office of Compliance.

- Regulatory Guidance, HFZ-323 (301) 427-8040

  Food and Drug Administration
  Center for Devices and Radiological Health
  8757 Georgia Avenue
  Silver Spring, MD 20910

21 CFR 801 and 809

LABELING

PART 801—LABELING

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801.427 Professional and patient labeling for intrauterine contraceptive devices.

AUTHORITY: Sec. 701, 52 Stat. 1055–1056 as amended (21 U.S.C. 371) unless otherwise noted.

SOURCE: 41 FR 6896, Feb. 13, 1976, unless otherwise noted.

Subpart A—General Labeling Provisions

§ 801.1 Medical devices; name and place of business of manufacturer, packer or distributor.

(a) The label of a device in package form shall specify conspicuously the name and place of business of the manufacturer, packer, or distributor.

(b) The requirement for declaration of the name of the manufacturer, packer, or distributor shall be deemed to be satisfied, in the case of a corporation, only by the actual corporate name which may be preceded or followed by the name of the particular division of the corporation. Abbreviations for "Company," "Incorporated," etc., may be used and "The" may be omitted. In the case of an individual, partnership, or association, the name under which the business is conducted shall be used.

(c) Where a device is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase that reveals the connection such person has with such device; such as, "Manufactured for ————", "Distributed by ————", or any other wording that expresses the facts.

(d) The statement of the place of business shall include the street address, city, State, and Zip Code; however, the street address may be omitted if it is shown in a current city directory or telephone directory. The requirement for inclusion of the ZIP Code shall apply only to consumer commodity labels developed or revised after the effective date of this section. In the case of nonconsumer packages, the ZIP Code shall appear on either the label or the labeling (including the invoice).

(e) If a person manufactures, packs, or distributes a device at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where such device was manufactured or packed or is to be distributed, unless such statement would be misleading.

§ 801.4 Meaning of "intended uses."

The words "intended uses" or words of similar import in §§ 801.5, 801.119, and 801.122 refer to the objective intent of the persons legally responsible for the labeling of devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the devices, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manu-

facturer knows, or has knowledge of facts that would give him notice that a device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a device which accords with such other uses to which the article is to be put.

§ 801.5 Medical devices; adequate directions for use.

"Adequate directions for use" means directions under which the layman can use a device safely and for the purposes for which it is intended. Section 801.4 defines "intended use". Directions for use may be inadequate because, among other reasons, of omission, in whole or in part, or incorrect specification of:

(a) Statements of all conditions, purposes, or uses for which such device is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the device is commonly used; except that such statements shall not refer to conditions, uses, or purposes for which the device can be safely used only under the supervision of a practitioner licensed by law and for which it is advertised solely to such practitioner.

(b) Quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions.

(c) Frequency of administration or application.

(d) Duration of administration or application.

(e) Time of administration or application, in relation to time of meals, time of onset of symptoms, or other time factors.

(f) Route or method of administration or application.

(g) Preparation for use, i.e., adjustment of temperature, or other manipulation or process.

§ 801.6 Medical devices; misleading statements.

Among representations in the labeling of a device which render such drug misbranded is a false or misleading representation with respect to another device or a drug or food or cosmetic.

§ 801.15 Medical devices; prominence of required label statements.

(a) A word, statement, or other information required by or under authority of the act to appear on the label may lack that prominence and conspicuousness required by section 502(c) of the act by reason, among other reasons, of:

(1) The failure of such word, statement, or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase;

(2) The failure of such word, statement, or information to appear on two or more parts or panels of the label, each of which has sufficient space therefor, and each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed;

(3) The failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement, or information;

(4) Insufficiency of label space for the prominent placing of such word, statement, or information, resulting from the use of label space for any word, statement, design, or device which is not required by or under authority of the act to appear on the label;

(5) Insufficiency of label space for the placing of such word, statement, or information, resulting from the use of label space to give materially greater conspicuousness to any other word, statement, or information, or to any design or device; or

(6) Smallness or style of type in which such word, statement, or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed, or graphic matter.

(b) No exemption depending on insufficiency of label space, as pre-

scribed in regulations promulgated under section 502(b) of the act, shall apply if such insufficiency is caused by:

(1) The use of label space for any word, statement, design, or device which is not required by or under authority of the act to appear on the label;

(2) The use of label space to give greater conspicuousness to any word, statement, or other information than is required by section 502(c) of the act; or

(3) The use of label space for any representation in a foreign language.

(c)(1) All words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear thereon in the English language: *Provided, however,* That in the case of articles distributed solely in the Commonwealth of Puerto Rico or in a Territory where the predominant language is one other than English, the predominant language may be substituted for English.

(2) If the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label shall appear thereon in the foreign language.

(3) If the labeling contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear on the labeling in the foreign language.

§ 801.16 Medical devices; Spanish-language version of certain required statements.

If devices restricted to prescription use only are labeled solely in Spanish for distribution in the Commonwealth of Puerto Rico where Spanish is the predominant language, such labeling is authorized under § 801.15(c).

Subpart B—[Reserved]

Subpart C—Labeling Requirements for Over-the-Counter Devices

§ 801.60 Principal display panel.

The term "principal display panel," as it applies to over-the-counter devices in package form and as used in this part, means the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale. The principal display panel shall be large enough to accommodate all the mandatory label information required to be placed thereon by this part with clarity and conspicuousness and without obscuring designs, vignettes, or crowding. Where packages bear alternate principal display panels, information required to be placed on the principal display panel shall be duplicated on each principal display panel. For the purpose of obtaining uniform type size in declaring the quantity of contents for all packages of substantially the same size, the term "area of the principal display panel" means the area of the side or surface that bears the principal display panel, which area shall be:

(a) In the case of a rectangular package where one entire side properly can be considered to be the principal display panel side, the product of the height times the width of that side;

(b) In the case of a cylindrical or nearly cylindrical container, 40 percent of the product of the height of the container times the circumference; and

(c) In the case of any other shape of container, 40 percent of the total surface of the container: *Provided, however,* That where such container presents an obvious "principal display panel" such as the top of a triangular or circular package, the area shall consist of the entire top surface.

In determining the area of the principal display panel, exclude tops, bottoms, flanges at the tops and bottoms of cans, and shoulders and necks of bottles or jars. In the case of cylindrical or nearly cylindrical containers, information required by this part to appear on the principal display panel

shall appear within that 40 percent of the circumference which is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale.

§ 801.61 Statement of identity.

(a) The principal display panel of an over-the-counter device in package form shall bear as one of its principal features a statement of the identity of the commodity.

(b) Such statement of identity shall be in terms of the common name of the device followed by an accurate statement of the principal intended action(s) of the device. Such statement shall be placed in direct conjunction with the most prominent display of the name and shall employ terms descriptive of the principal intended action(s). The indications for use shall be included in the directions for use of the device, as required by section 502(f)(1) of the act and by the regulations in this part.

(c) The statement of identity shall be presented in bold face type on the principal display panel, shall be in a size reasonably related to the most prominent printed matter on such panel, and shall be in lines generally parallel to the base on which the package rests as it is designed to be displayed.

§ 801.62 Declaration of net quantity of contents.

(a) The label of an over-the-counter device in package form shall bear a declaration of the net quantity of contents. This shall be expressed in the terms of weight, measure, numerical count, or a combination of numerical count and weight, measure, or size: *Provided*, That:

(1) In the case of a firmly established general consumer usage and trade custom of declaring the quantity of a device in terms of linear measure or measure of area, such respective term may be used. Such term shall be augmented when necessary for accuracy of information by a statement of the weight, measure, or size of the individual units or of the entire device.

(2) If the declaration of contents for a device by numerical count does not give accurate information as to the quantity of the device in the package, it shall be augmented by such statement of weight, measure, or size of the individual units or of the total weight, measure, or size of the device as will give such information; for example, "100 tongue depressors, adult size", "1 rectal syringe, adult size", etc. Whenever the Commissioner determines for a specific packaged device that an existing practice of declaring net quantity of contents by weight, measure, numerical count, or a combination of these does not facilitate value comparisions by consumers, he shall by regulation designate the appropriate term or terms to be used for such article.

(b) Statements of weight of the contents shall be expressed in terms of avoirdupois pound and ounce. A statement of liquid measure of the contents shall be expressed in terms of the U.S. gallon of 231 cubic inches and quart, pint, and fluid-ounce subdivisions thereof, and shall express the volume at 68° F (20° C). See also paragraph (p) of this section.

(c) The declaration may contain common or decimal fractions. A common fraction shall be in terms of halves, quarters, eighths, sixteenths, or thirty-seconds; except that if there exists a firmly established, general consumer usage and trade custom of employing different common fractions in the net quantity declaration of a particular commodity, they may be employed. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than two places. A statement that includes small fractions of an ounce shall be deemed to permit smaller variations than one which does not include such fractions.

(d) The declaration shall be located on the principal display panel of the label, and with respect to packages bearing alternate principal panels it shall be duplicated on each principal display panel.

(e) The declaration shall appear as a distinct item on the principal display panel, shall be separated, by at least a space equal to the height of the lettering used in the declaration, from other printed label information appearing above or below the declaration and, by

at least a space equal to twice the width of the letter "N" of the style of type used in the quantity of contents statement, from other printed label information appearing to the left or right of the declaration. It shall not include any term qualifying a unit of weight, measure, or count, such as "giant pint" and "full quart", that tends to exaggerate. It shall be placed on the principal display panel within the bottom 30 percent of the area of the label panel in lines generally parallel to the base on which the package rests as it is designed to be displayed: *Provided*, That:

(1) On packages having a principal display panel of 5 square inches or less the requirement for placement within the bottom 30 percent of the area of the label panel shall not apply when the declaration of net quantity of contents meets the other requirements of this part; and

(2) In the case of a device that is marketed with both outer and inner retail containers bearing the mandatory label information required by this part and the inner container is not intended to be sold separately, the net quantity of contents placement requirement of this section applicable to such inner container is waived.

(3) The principal display panel of a device marketed on a display card to which the immediate container is affixed may be considered to be the display panel of the card, and the type size of the net quantity of contents statement is governed by the dimensions of the display card.

(f) The declaration shall accurately reveal the quantity of device in the package exclusive of wrappers and other material packed therewith.

(g) The declaration shall appear in conspicuous and easily legible boldface print or type in distinct contrast (by typography, layout, color, embossing, or molding) to other matter on the package; except that a declaration of net quantity blown, embossed, or molded on a glass or plastic surface is permissible when all label information is so formed on the surface. Requirements of conspicuousness and legibility shall include the specifications that:

(1) The ratio of height to width of the letter shall not exceed a differential of 3 units to 1 unit, i.e., no more than 3 times as high as it is wide.

(2) Letter heights pertain to upper case or capital letters. When upper and lower case or all lower case letters are used, it is the lower case letter "o" or its equivalent that shall meet the minimum standards.

(3) When fractions are used, each component numeral shall meet one-half the minimum height standards.

(h) The declaration shall be in letters and numerals in a type size established in relationship to the area of the principal display panel of the package and shall be uniform for all packages of substantially the same size by complying with the following type specifications:

(1) Not less than one-sixteenth inch in height on packages the principal display panel of which has an area of 5 square inches or less.

(2) Not less than one-eighth inch in height on packages the principal display panel of which has an area of more than 5 but not more than 25 square inches.

(3) Not less than three-sixteenths inch in height on packages the principal display panel of which has an area of more than 25 but not more than 100 square inches.

(4) Not less than one-fourth inch in height on packages the principal display panel of which has an area of more than 100 square inches, except not less than one-half inch in height if the area is more than 400 square inches.

Where the declaration is blown, embossed, or molded on a glass or plastic surface rather than by printing, typing, or coloring, the lettering sizes specified in paragraphs (h)(1) through (4) of this section shall be increased by one-sixteenth of an inch.

(i) On packages containing less than 4 pounds or 1 gallon and labeled in terms of weight or fluid measure:

(1) The declaration shall be expressed both in ounces, with identification by weight or by liquid measure and, if applicable (1 pound or 1 pint or more) followed in parentheses by a declaration in pounds for weight units, with any remainder in terms of ounces

or common or decimal fractions of the pound (see examples set forth in paragraph (k) (1) and (2) of this section), or in the case of liquid measure, in the largest whole units (quarts, quarts and pints, or pints, as appropriate) with any remainder in terms of fluid ounces or common or decimal fractions of the pint or quart (see examples set forth in paragraph (k)(3) and (4) of this section). If the net weight of the package is less than 1 ounce avoirdupois or the net fluid measure is less than 1 fluid ounce, the declaration shall be in terms of common or decimal fractions of the respective ounce and not in terms of drams.

(2) The declaration may appear in more than one line. The term "net weight" shall be used when stating the net quantity of contents in terms of weight. Use of the terms "net" or "net contents" in terms of fluid measure or numerical count is optional. It is sufficient to distinguish avoirdupois ounce from fluid ounce through association of terms; for example, "Net wt. 6 oz" or "6 oz net wt.," and "6 fl oz" or "net contents 6 fl oz."

(j) On packages containing 4 pounds or 1 gallon or more and labeled in terms of weight or fluid measure, the declaration shall be expressed in pounds for weight units with any remainder in terms of ounces or common or decimal fractions of the pound; in the case of fluid measure, it shall be expressed in the largest whole unit, i.e., gallons, followed by common or decimal fractions of a gallon or by the next smaller whole unit or units (quarts or quarts and pints), with any remainder in terms of fluid ounces or common or decimal fractions of the pint or quart; see paragraph (k) (5) of this section.

(k) Examples:

(1) A declaration of 1½ pounds weight shall be expressed as "net wt. 24 oz (1 lb 8 oz)," or "Net wt. 24 oz (1½ lb)" or "Net wt. 24 oz (1.5 lb)."

(2) A declaration of three-fourths pound avoirdupois weight shall be expressed as "Net wt. 12 oz.".

(3) A declaration of 1 quart liquid measure shall be expressed as "Net contents 32 fl oz (1 qt)" or "32 fl oz (1 qt)."

(4) A declaration of 1¾ quarts liquid measure shall be expressed as, "Net contents 56 fl oz (1 qt 1 pt 8 oz)" or "Net contents 56 fl oz (1 qt 1.5 pt)," but not in terms of quart and ounce such as "Net contents 56 fl oz (1 qt 24 oz)."

(5) A declaration of 2½ gallons liquid measure shall be expressed as "Net contents 2 gal 2 qt", "Net contents 2.5 gallons," or "Net contents 2½ gal" but not as "2 gal 4 pt".

(l) For quantities, the following abbreviations and none other may be employed. Periods and plural forms are optional:

gallon gal	milliliter ml
quart qt	cubic centimeter cc
pint pt	yard yd
ounce oz	feet or foot ft
pound lb	inch in
grain gr	meter m
kilogram kg	centimeter cm
gram g	millimeter mm
milligram mg	fluid fl
microgram mcg	square sq
liter l	weight wt

(m) On packages labeled in terms of linear measure, the declaration shall be expressed both in terms of inches and, if applicable (1 foot or more), the largest whole units (yards, yards and feet, feet). The declaration in terms of the largest whole units shall be in parentheses following the declaration in terms of inches and any remainder shall be in terms of inches or common or decimal fractions of the foot or yard; if applicable, as in the case of adhesive tape, the initial declaration in linear inches shall be preceded by a statement of the width. Examples of linear measure are "86 inches (2 yd 1 ft 2 in)", "90 inches (2½ yd)", "30 inches (2.5 ft)", "¾ inch by 36 in (1 yd)", etc.

(n) On packages labeled in terms of area measure, the declaration shall be expressed both in terms of square inches and, if applicable (1 square foot or more), the largest whole square unit (square yards, square yards and square feet, square feet). The declaration in terms of the largest whole units shall be in parentheses following the declaration in terms of square inches and any remainder shall be in terms of square inches or common or decimal fractions of the square foot or square yard; for example, "158 sq inches (1 sq ft 14 sq in)".

(o) Nothing in this section shall prohibit supplemental statements at locations other than the principal display panel(s) describing in nondeceptive terms the net quantity of contents, provided that such supplemental statements of net quantity of contents shall not include any term qualifying a unit of weight, measure, or count that tends to exaggerate the amount of the device contained in the package; for example, "giant pint" and "full quart". Dual or combination declarations of net quantity of contents as provided for in paragraphs (a) and (i) of this section are not regarded as supplemental net quantity statements and shall be located on the principal display panel.

(p) A separate statement of net quantity of contents in terms of the metric system of weight or measure is not regarded as a supplemental statement and an accurate statement of the net quantity of contents in terms of the metric system of weight or measure may also appear on the principal display panel or on other panels.

(q) The declaration of net quantity of contents shall express an accurate statement of the quantity of contents of the package. Reasonable variations caused by loss or gain of moisture during the course of good distribution practice or by unavoidable deviations in good manufacturing practice will be recognized. Variations from stated quantity of contents shall not be unreasonably large.

Subpart D—Exemptions From Adequate Directions for Use

§ 801.109 Prescription devices.

A device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which "adequate directions for use" cannot be prepared, shall be exempt from section 502(f)(1) of the act if all the following conditions are met:

(a) The device is:

(1)(i) In the possession of a person, or his agents or employees, regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of such device; or

(ii) In the possession of a practitioner, such as physicians, dentists, and veterinarians, licensed by law to use or order the use of such device; and

(2) Is to be sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice.

(b) The label of the device, other than surgical instruments, bears:

(1) The statement "Caution: Federal law restricts this device to sale by or on the order of a ————", the blank to be filled with the word "physician", "dentist", "veterinarian", or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of the device; and

(2) The method of its application or use.

(c) Labeling on or within the package from which the device is to be dispensed bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented: *Provided, however,* That such information may be omitted from the dispensing package if, but only if, the article is a device for which directions, hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device. Upon written request, stating reasonable grounds therefor, the Commissioner will offer an opinion on a proposal to omit such information from the dispensing package under this proviso.

(d) Any labeling, as defined in section 201(m) of the act, whether or not it is on or within a package from which the device is to be dispensed, distributed by or on behalf of the manufacturer, packer, or distributor of the device, that furnishes or purports to furnish information for use of the device contains adequate informa-

tion for such use, including indications, effects, routes, methods, and frequency and duration of administration and any relevant hazards, contraindications, side effects, and precautions, under which practitioners licensed by law to employ the device can use the device safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented. This information will not be required on so-called reminder—piece labeling which calls attention to the name of the device but does not include indications or other use information.

(e) All labeling, except labels and cartons, bearing information for use of the device also bears the date of the issuance or the date of the latest revision of such labeling.

§ 801.110 Retail exemption for prescription devices.

A device subject to § 801.109 shall be exempt at the time of delivery to the ultimate purchaser or user from section 502(f)(1) of the act if it is delivered by a licensed practitioner in the course of his professional practice or upon a prescription or other order lawfully issued in the course of his professional practice, with labeling bearing the name and address of such licensed practitioner and the directions for use and cautionary statements, if any, contained in such order.

§ 801.116 Medical devices having commonly known directions.

A device shall be exempt from section 502(f)(1) of the act insofar as adequate directions for common uses thereof are known to the ordinary individual.

§ 801.119 In vitro diagnostic products.

A product intended for use in the diagnosis of disease and which is an in vitro diagnostic product as defined in § 809.3(a) of this chapter shall be deemed to be in compliance with the requirements of this section and section 502(f)(1) of the act if it meets the requirements of § 809.10 of this chapter.

§ 801.122 Medical devices for processing, repacking, or manufacturing.

A device intended for processing, repacking, or use in the manufacture of another drug or device shall be exempt from section 502(f)(1) of the act if its label bears the statement "Caution: For manufacturing, processing, or repacking".

§ 801.125 Medical devices for use in teaching, law enforcement, research, and analysis.

A device subject to § 801.109 shall be exempt from section 502(f)(1) of this act if shipped or sold to, or in the possession of, persons regularly and lawfully engaged in instruction in pharmacy, chemistry, or medicine not involving clinical use, or engaged in law enforcement, or in research not involving clinical use, or in chemical analysis, or physical testing, and is to be used only for such instruction, law enforcement, research, analysis, or testing.

§ 801.127 Medical devices; expiration of exemptions.

(a) If a shipment or delivery, or any part thereof, of a device which is exempt under the regulations in this section is made to a person in whose possession the article is not exempt, or is made for any purpose other than those specified, such exemption shall expire, with respect to such shipment or delivery or part thereof, at the beginning of that shipment or delivery. The causing of an exemption to expire shall be considered an act which results in such device being misbranded unless it is disposed of under circumstances in which it ceases to be a drug or device.

(b) The exemptions conferred by §§ 801.119, 801.122, and 801.125 shall continue until the devices are used for the purposes for which they are exempted, or until they are relabeled to comply with section 502(f)(1) of the act. If, however, the device is converted, or manufactured into a form limited to prescription dispensing, no exemption shall thereafter apply to the article unless the device is labeled as required by § 801.109.

Subpart E—Other Exemptions

§ 801.150 Medical devices; processing, labeling, or repacking.

(a) Except as provided by paragraphs (b) and (c) of this section, a shipment or other delivery of a device which is, in accordance with the practice of the trade, to be processed, labeled, or repacked, in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling and packaging requirements of section 502(b) and (f) of the act if:

(1) The person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such device is to be processed, labeled, or repacked; or

(2) In case such person is not such operator, such shipment or delivery is made to such establishment under a written agreement, signed by and containing the post office addresses of such person and such operator, and containing such specifications for the processing, labeling, or repacking, as the case may be, of such device in such establishment as will insure, if such specifications are followed, that such device will not be adulterated or misbranded within the meaning of the act upon completion of such processing, labeling, or repacking. Such person and such operator shall each keep a copy of such agreement until 2 years after the final shipment or delivery of such device from such establishment, and shall make such copies available for inspection at any reasonable hour to any officer or employee of the Department who requests them.

(b) An exemption of a shipment or other delivery of a device under paragraph (a) (1) of this section shall, at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment, become void ab initio if the device comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the act when so removed.

(c) An exemption of a shipment or other delivery of a device under paragraph (a)(2) of this section shall become void ab initio with respect to the person who introduced such shipment or delivery into interstate commerce upon refusal by such person to make available for inspection a copy of the agreement, as required by such paragraph (a)(2).

(d) An exemption of a shipment or other delivery of a device under paragraph (a)(2) of this section shall expire:

(1) At the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment if the device comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the act when so removed; or

(2) Upon refusal by the operator of the establishment where such device is to be processed, labeled, or repacked, to make available for inspection a copy of the agreement, as required by such clause.

(e) As it is a common industry practice to manufacture and/or assemble, package, and fully label a device as sterile at one establishment and then ship such device in interstate commerce to another establishment or to a contract sterilizer for sterilization, the Food and Drug Administration will initiate no regulatory action against the device as misbranded or adulterated when the nonsterile device is labeled sterile, provided all the following conditions are met:

(1) There is in effect a written agreement which:

(i) Contains the names and post office addresses of the firms involved and is signed by the person authorizing such shipment and the operator or person in charge of the establishment receiving the devices for sterilization.

(ii) Provides instructions for maintaining proper records or otherwise accounting for the number of units in each shipment to insure that the number of units shipped is the same as the number received and sterilized.

(iii) Acknowledges that the device is nonsterile and is being shipped for further processing, and

(iv) States in detail the sterilization process, the gaseous mixture or other

media, the equipment, and the testing method or quality controls to be used by the contract sterilizer to assure that the device will be brought into full compliance with the Federal Food, Drug, and Cosmetic Act.

(2) Each pallet, carton, or other designated unit is conspicuously marked to show its nonsterile nature when it is introduced into and is moving in interstate commerce, and while it is being held prior to sterilization. Following sterilization, and until such time as it is established that the device is sterile and can be released from quarantine, each pallet, carton, or other designated unit is conspicuously marked to show that it has not been released from quarantine, e.g., "sterilized—awaiting test results" or an equivalent designation.

Subparts F–G—[Reserved]

Subpart H—Special Requirements for Specific Devices

§ 801.403 Specific medical devices; recommended warning and caution statements.

DENTURE RELINERS, PADS, AND CUSHIONS.

Warning—For temporary use only. Long term use of this product may lead to faster bone loss, continuing irritation, sores, and tumors. For Use Only Until A Dentist Can Be Seen.

DENTURE REPAIR KITS.

Warning—For emergency repairs only. Long term use of home-repaired dentures may cause faster bone loss, continuing irritation, sores, and tumors. This kit for emergency use only. See Dentist Without Delay.

INFRARED GENERATORS (INCLUDING HEATING PADS).

Warning—Use carefully. May cause serious burns. Do not use over insensitive skin areas or in the presence of poor circulation. The unattended use of infrared heat by children or incapacitated persons may be dangerous.

INSULIN SYRINGES.

Warning—For patients who mix two types of insulin: Do not change: (a) The order of mixing that the physician has prescribed or (b) the model and brand of the syringe or needle without first consulting your physician or pharmacist. Failure to heed this warning can result in dosage error.

MECHANICAL MASSAGERS AND VIBRATORS.

Warning—This device should not be used over swollen or inflamed areas or skin eruptions. Do not use in unexplained calf pain. Consult physician.

STEAM OR TURKISH BATH.

Warning—Elderly persons or those suffering from heart disease or high blood pressure should not use this device unless directed by physician.

ULTRAVIOLET GENERATORS.

Warning—Wear protective goggles during use to avoid eye injury. Serious burns may be caused by exposure in excess of recommended dosage. Do not use over skin eruptions unless directed by physician.

§ 801.405 Labeling of articles intended for lay use in the repairing and/or refitting of dentures.

(a) The American Dental Association and leading dental authorities have advised the Food and Drug Administration of their concern regarding the safety of denture reliners, repair kits, pads, cushions, and other articles marketed and labeled for lay use in the repairing, refitting, or cushioning of ill-fitting, broken, or irritating dentures. It is the opinion of dental authorities and the Food and Drug Administration that to properly repair and properly refit dentures a person must have professional knowledge and specialized technical skill. Laymen cannot be expected to maintain the original vertical dimension of occlusion and the centric relation essential in the proper repairing or refitting of dentures. The continued wearing of improperly repaired or refitted dentures may cause acceleration of bone resorption, soft tissue hyperplasia, and other irreparable damage to the oral cavity. Such articles designed for lay use should be limited to emergency or temporary sit-

uations pending the services of a licensed dentist.

(b) The Food and Drug Administration therefore regards such articles as unsafe and misbranded under the Federal Food, Drug, and Cosmetic Act, unless the labeling:

(1) (i) Limits directions for use for denture repair kits to emergency repairing pending unavoidable delay in obtaining professional reconstruction of the denture;

(ii) Limits directions for use for denture reliners, pads, and cushions to temporary refitting pending unavoidable delay in obtaining professional reconstruction of the denture;

(2) Contains in a conspicuous manner the word "emergency" preceding and modifying each indication-for-use statement for denture repair kits and the word "temporary" preceding and modifying each indication-for-use statement for reliners, pads, and cushions; and

(3) Includes a conspicuous warning statement to the effect:

(i) For denture repair kits: *"Warning—For emergency repairs only.* Long term use of home-repaired dentures may cause faster bone loss, continuing irritation, sores, and tumors. This kit for emergency use only. See Dentist Without Delay."

(ii) For denture reliners, pads, and cushions: *"Warning—For temporary use only.* Longterm use of this product may lead to faster bone loss, continuing irritation, sores, and tumors. For Use Only Until a Dentist Can Be Seen."

(c) Adequate directions for use require full information of the temporary and emergency use recommended in order for the layman to understand the limitations of usefulness, the reasons therefor, and the importance of adhering to the warnings. Accordingly, the labeling should contain substantially the following information:

(1) For denture repair kits: Special training and tools are needed to repair dentures to fit properly. Home-repaired dentures may cause irritation to the gums and discomfort and tiredness while eating. Long term use may lead to more troubles, even permanent changes in bones, teeth, and gums, which may make it impossible to wear dentures in the future. For these reasons, dentures repaired with this kit should be used only in an emergency until a dentist can be seen. Dentures that don't fit properly cause irritation and injury to the gums and faster bone loss, which is permanent. Dentures that don't fit properly cause gum changes that may require surgery for correction. Continuing irritation and injury may lead to cancer in the mouth. You must see your dentist as soon as possible.

(2) For denture reliners, pads, and cushions: Use of these preparations or devices may temporarily decrease the discomfort; however, their use will not make the denture fit properly. Special training and tools are needed to repair a denture to fit properly. Dentures that do not fit properly cause irritation and injury to the gums and faster bone loss, which is permanent and may require a completely new denture. Changes in the gums caused by dentures that do not fit properly may require surgery for correction. Continuing irritation and injury may lead to cancer in the mouth. You must see your dentist as soon as possible.

(3) If the denture relining or repairing material forms a permanent bond with the denture, a warning statement to the following effect should be included: "This reliner becomes fixed to the denture and a completely new denture may be required because of its use."

(d) Labeling claims exaggerating the usefulness or the safety of the material or failing to disclose all facts relevant to the claims of usefulness will be regarded as false and misleading under sections 201(n) and 502(a) of the Federal Food, Drug, and Cosmetic Act.

(e) Regulatory action may be initiated with respect to any article found within the jurisdiction of the act contrary to the provisions of this policy statement after 90 days following the date of publication of this section in the FEDERAL REGISTER.

§ 801.408 Pessaries for intracervical and intrauterine use.

(a) Because of the limited evidence previously available concerning the hazards attending the use of intracervical and intrauterine pessaries, the

shipment of such devices within the jurisdiction of the Federal Food, Drug, and Cosmetic Act with labeling limiting them to sale only on prescription, has not been subjected to regulatory proceedings. A recent survey shows that it is now the consensus of medical opinion among experts qualified by scientific training and experience to evaluate the safety of such devices that stem-type and wing-type intercervical and intrauterine pessaries are too dangerous for use under any form of labeling and serve no useful purpose. This opinion is particularly applicable to pessaries offered or intended for contraceptive use. These views do not apply to those pessaries, made with hollow tubes, intended solely for use when necessary to maintain drainage from the uterine cavity.

(b) On the basis of this consensus of expert opinion and the supporting evidence of many known injuries, the Food and Drug Administration concludes that stem-type and wing-type intracervical and intrauterine pessaries are dangerous to health, and regardless of their labeling, may be shown to be misbranded within the meaning of sections 502(f) (1) and (2) and 502(j) of the Federal Food, Drug, and Cosmetic Act. It is recommended that distributors of these devices remove them from the interstate market at once. Regulatory action may be instituted in connection with any such devices found within the jurisdiction of the act.

§ 801.410 Use of impact-resistant lenses in eyeglasses and sunglasses.

(a) Examination of data available on the frequency of eye injuries resulting from the shattering of ordinary crown glass lenses indicates that the use of such lenses constitutes an avoidable hazard to the eye of the wearer.

(b) The consensus of the ophthalmic community is that the number of eye injuries would be substantially reduced by the use in eyeglasses and sunglasses of impact-resistant lenses.

(c)(1) To protect the public more adequately from potential eye injury, eyeglasses and sunglasses must be fitted with impact-resistant lenses, except in those cases where the physician or optometrist finds that such lenses will not fulfill the visual requirements of the particular patient, directs in writing the use of other lenses, and gives written notification thereof to the patient.

(2) The physician or optometrist shall have the option of ordering glass lenses, plastic lenses, or laminated glass lenses made impact resistant by any method; however, all such lenses shall be capable of withstanding the impact test described in paragraph (d)(2) of this section.

(3) Each finished impact-resistant glass lens for prescription use shall be individually tested for impact resistance and shall be capable of withstanding the impact test described in paragraph (d)(2) of this section. Raised multifocal lenses shall be impact resistant but need not be tested beyond initial design testing. Prism segment multifocal, slab-off prism, lenticular cataract, iseikonic, depressed segment one-piece multifocal, bioconcave, myodisc and minus lenticular, custom laminate and cemented assembly lenses shall be impact resistant but need not be subjected to impact testing. To demonstrate that all other types of impact-resistant lenses, including impact-resistant laminated glass lenses (i.e., lenses other than those described in the three preceding sentences of this paragraph (c)(3)), are capable of withstanding the impact test described in this regulation, the manufacturer of these lenses shall subject to an impact test a statistically significant sampling of lenses from each production batch, and the lenses so tested shall be representative of the finished forms as worn by the wearer, including finished forms that are of minimal lens thickness and have been subjected to any treatment used to impart impact resistance. All nonprescription lenses and plastic prescription lenses tested on the basis of statistical significance shall be tested in uncut-finished or finished form.

(d)(1) For the purpose of this regulation, the impact test described in paragraph (d)(2) of this section shall be the "referee test," defined as "one which will be utilized to determine compliance with a regulation." The referee test provides the Food and

Drug Administration with the means of examining a medical device for performance and does not inhibit the manufacturer from using equal or superior test methods. A lens manufacturer shall conduct tests of lenses using the impact test described in paragraph (d)(2) of this section or any equal or superior test. Whatever test is used, the lenses shall be capable of withstanding the impact test described in paragraph (d)(2) of this section if the Food and Drug Administration examines them for performance.

(2) In the impact test, a ⅝-inch steel ball weighing approximately 0.56 ounce is dropped from a height of 50 inches upon the horizontal upper surface of the lens. The ball shall strike within a ⅝-inch diameter circle located at the geometric center of the lens. The ball may be guided but not restricted in its fall by being dropped through a tube extending to within approximately 4 inches of the lens. To pass the test, the lens must not fracture; for the purpose of this section, a lens will be considered to have fractured if it cracks through its entire thickness, including a laminar layer, if any, and across a complete diameter into two or more separate pieces, or if any lens material visible to the naked eyes becomes detached from the ocular surface. The test shall be conducted with the lens supported by a tube (1-inch inside diameter, 1¼-inch outside diameter, and approximately 1-inch high) affixed to a rigid iron or steel base plate. The total weight of the base plate and its rigidly attached fixtures shall be not less than 27 pounds. For lenses of small minimum diameter, a support tube having an outside diameter of less than 1¼ inches may be used. The support tube shall be made of rigid acrylic plastic, steel, or other suitable substance and shall have securely bonded on the top edge a ⅛- by ⅛-inch neoprene gasket having a hardness of 40±5, as determined by ASTM Method D 1415; [1] a minimum tensile strength of 1,200 pounds, as determined by ASTM Method D 412; [1] and a minimum ultimate elongation of 400 percent, as determined by ASTM Method D 412 (ASTM Methods D 412 and D 1415 are incorporated by reference). The diameter or contour of the lens support may be modified as necessary so that the ⅛- by ⅛-inch neoprene gasket supports the lens at its periphery.

(e) Copies of invoice(s), shipping document(s), and records of sale or distribution of all impact resistant lenses, including finished eyeglasses and sunglasses, shall be kept and maintained for a period of 3 years; however, the names and addresses of individuals purchasing nonprescription eyeglasses and sunglasses at the retail level need not be kept and maintained by the retailer. The records kept in compliance with this paragraph shall be made available upon request at all reasonable hours by any officer or employee of the Food and Drug Administration or by any other officer or employee acting on behalf of the Secretary of Health, Education, and Welfare and such officer or employee shall be permitted to inspect and copy such records, to make such inventories of stock as he deems necessary, and otherwise to check the correctness of such inventories.

(f) In addition, those persons conducting tests in accordance with paragraph (d) of this section shall maintain the results thereof and a description of the test method and of the test apparatus for a period of 3 years. These records shall be made available upon request at any reasonable hour by any officer or employee acting on behalf of the Secretary of Health, Education, and Welfare. The persons conducting tests shall permit the officer or employee to inspect and copy the records, to make such inventories of stock as the officer or employee deems necessary, and otherwise to check the correctness of the inventories.

(g) For the purpose of this section, the term "manufacturer" includes an importer for resale. Such importer may have the tests required by paragraph (d) of this section conducted in the country of origin but must make the results thereof available, upon request, to the Food and Drug Administration, as soon as practicable.

[1] Copies may be obtained from: American Society for Testing Materials (ASTM), 1916 Race St., Philadelphia, PA 19103.

(h) All lenses must be impact-resistant except when the physician or optometrist finds that impact-resistant lenses will not fulfill the visual requirements for a particular patient.

(i) This statement of policy does not apply to contact lenses.

(Secs. 201, 501, 502, 519, 701(a), 52 Stat. 1040-1042 as amended, 1049-1051 as amended, 1055, 90 Stat. 564-565 (21 U.S.C. 321, 351, 352, 360l, 371(a)))

[41 FR 6896, Feb. 13, 1976, as amended at 44 FR 20678, Apr. 6, 1979]

§ 801.415 Maximum acceptable level of ozone.

(a) Ozone is a toxic gas with no known useful medical application in specific, adjunctive, or preventive therapy. In order for ozone to be effective as a germicide, it must be present in a concentration far greater than that which can be safely tolerated by man and animals.

(b) Although undesirable physiological effects on the central nervous system, heart, and vision have been reported, the predominant physiological effect of ozone is primary irritation of the mucous membranes. Inhalation of ozone can cause sufficient irritation to the lungs to result in pulmonary edema. The onset of pulmonary edema is usually delayed for some hours after exposure; thus, symptomatic response is not a reliable warning of exposure to toxic concentrations of ozone. Since olfactory fatigue develops readily, the odor of ozone is not a reliable index of atmospheric ozone concentration.

(c) A number of devices currently on the market generate ozone by design or as a byproduct. Since exposure to ozone above a certain concentration can be injurious to health, any such device will be considered adulterated and/or misbranded within the meaning of sections 501 and 502 of the act if it is used or intended for use under the following conditions:

(1) In such a manner that it generates ozone at a level in excess of 0.05 part per million by volume of air circulating through the device or causes an accumulation of ozone in excess of 0.05 part per million by volume of air (when measured under standard conditions at 25° C (77° F) and 760 millimeters of mercury) in the atmosphere of enclosed space intended to be occupied by people for extended periods of time, e.g., houses, apartments, hospitals, and offices. This applies to any such device, whether portable or permanent or part of any system, which generates ozone by design or as an inadvertent or incidental product.

(2) To generate ozone and release it into the atmosphere in hospitals or other establishments occupied by the ill or infirm.

(3) To generate ozone and release it into the atmosphere and does not indicate in its labeling the maximum acceptable concentration of ozone which may be generated (not to exceed 0.05 part per million by volume of air circulating through the device) as established herein and the smallest area in which such device can be used so as not to produce an ozone accumulation in excess of 0.05 part per million.

(4) In any medical condition for which there is no proof of safety and effectiveness.

(5) To generate ozone at a level less than 0.05 part per million by volume of air circulating through the device and it is labeled for use as a germicide or deodorizer.

(d) This section does not affect the present threshold limit value of 0.10 part per million (0.2 milligram per cubic meter) of ozone exposure for an 8-hour-day exposure of industrial workers as recommended by the American Conference of Governmental Industrial Hygienists.

(e) The method and apparatus specified in 40 CFR Part 50, or any other equally sensitive and accurate method, may be employed in measuring ozone pursuant to this section.

§ 801.417 Chlorofluorocarbon propellants.

The use of chlorofluorocarbon in devices as propellants in self-pressurized containers is generally prohibited except as provided in § 2.125 of this chapter.

(Secs. 301, 402, 409, 501, 502, 505, 507, 512, 601, 52 Stat. 1042-1043 as amended, 1046-1047 as amended, 1049-1054 as amended, 1055, 57 Stat. 463 as amended, 72 Stat. 1785-1788 as amended, 82 Stat. 343-351 (21 U.S.C. 331, 342, 348, 351, 352, 355, 357, 360b, 361) sec. 102(2), 83 Stat. 853 (42 U.S.C. 4332))

[43 FR 11318, Mar. 17, 1978]

§ 801.420 Hearing aid devices; professional and patient labeling.

(a) *Definitions for the purposes of this section and § 801.421.* (1) "Hearing aid" means any wearable instrument or device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing.

(2) "Ear specialist" means any licensed physician who specializes in diseases of the ear and is medically trained to identify the symptoms of deafness in the context of the total health of the patient, and is qualified by special training to diagnose and treat hearing loss. Such physicians are also known as otolaryngologists, otologists, and otorhinolaryngologists.

(3) "Dispenser" means any person, partnership, corporation, or association engaged in the sale, lease, or rental of hearing aids to any member of the consuming public or any employee, agent, sales person, and/or representative of such a person, partnership, corporation, or association.

(4) "Audiologist" means any person qualified by training and experience to specialize in the evaluation and rehabilitation of individuals whose communication disorders center in whole or in part in the hearing function. In some states audiologists must satisfy specific requirements for licensure.

(5) "Sale" or "purchase" includes any lease or rental of a hearing aid to a member of the consuming public who is a user or prospective user of a hearing aid.

(6) "Used hearing aid" means any hearing aid that has been worn for any period of time by a user. However, a hearing aid shall not be considered "used" merely because it has been worn by a prospective user as a part of a bona fide hearing aid evaluation conducted to determine whether to select that particular hearing aid for that prospective user, if such evaluation has been conducted in the presence of the dispenser or a hearing aid health professional selected by the dispenser to assist the buyer in making such a determination.

(b) *Label requirements for hearing aids.* Hearing aids shall be clearly and permanently marked with:

(1) The name of the manufacturer or distributor, the model name or number, the serial number, and the year of manufacture.

(2) A "+" symbol to indicate the positive connection for battery insertion, unless it is physically impossible to insert the battery in the reversed position.

(c) *Labeling requirements for hearing aids*—(1) *General.* All labeling information required by this paragraph shall be included in a User Instructional Brochure that shall be developed by the manufacturer or distributor, shall accompany the hearing aid, and shall be provided to the prospective user by the dispenser of the hearing aid in accordance with § 801.421(c). The User Instructional Brochure accompanying each hearing aid shall contain the following information and instructions for use, to the extent applicable to the particular requirements and characteristics of the hearing aid:

(i) An illustration(s) of the hearing aid, indicating operating controls, user adjustments, and battery compartment.

(ii) Information on the function of all controls intended for user adjustment.

(iii) A description of any accessory that may accompany the hearing aid, e.g., accessories for use with a television or telephone.

(iv) Specific instructions for:

(*a*) Use of the hearing aid.

(*b*) Maintenance and care of the hearing aid, including the procedure to follow in washing the earmold, when replacing tubing on those hearing aids that use tubing, and in storing the hearing aid when it will not be used for an extended period of time.

(*c*) Replacing or recharging the batteries, including a generic designation of replacement batteries.

(v) Information on how and where to obtain repair service, including at least one specific address where the user can go, or send the hearing aid to, to obtain such repair service.

(vi) A description of commonly occurring avoidable conditions that could adversely affect or damage the hearing aid, such as dropping, immersing, or exposing the hearing aid to excessive heat.

(vii) Identification of any known side effects associated with the use of a hearing aid that may warrant consultation with a physician, e.g., skin irritation and accelerated accumulation of cerumen (ear wax).

(viii) A statement that a hearing aid will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions.

(ix) A statement that in most cases infrequent use of a hearing aid does not permit a user to attain full benefit from it.

(x) A statement that the use of a hearing aid is only part of hearing habilitation and may need to be supplemented by auditory training and instruction in lipreading.

(xi) The warning statement required by paragraph (c)(2) of this section.

(xii) The notice for prospective hearing aid users required by paragraph (c)(3) of this section.

(xiii) The technical data required by paragraph (c)(4) of this section, unless such data is provided in separate labeling accompanying the device.

(2) *Warning statement.* The User Instructional Brochure shall contain the following warning statement:

WARNING TO HEARING AID DISPENSERS

A hearing aid dispenser should advise a prospective hearing aid user to consult promptly with a licensed physician (preferably an ear specialist) before dispensing a hearing aid if the hearing aid dispenser determines through inquiry, actual observation, or review of any other available information concerning the prospective user, that the prospective user has any of the following conditions:

(i) Visible congenital or traumatic deformity of the ear.

(ii) History of active drainage from the ear within the previous 90 days.

(iii) History of sudden or rapidly progressive hearing loss within the previous 90 days.

(iv) Acute or chronic dizziness.

(v) Unilateral hearing loss of sudden or recent onset within the previous 90 days.

(vi) Audiometric air-bone gap equal to or greater than 15 decibels at 500 hertz (Hz), 1,000 Hz, and 2,000 Hz.

(vii) Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.

(viii) Pain or discomfort in the ear.

Special care should be exercised in selecting and fitting a hearing aid whose maximum sound pressure level exceeds 132 decibels because there may be risk of impairing the remaining hearing of the hearing aid user. (This provision is required only for those hearing aids with a maximum sound pressure capability greater than 132 decibels (dB).)

(3) *Notice for prospective hearing aid users.* The User Instructional Brochure shall contain the following notice:

IMPORTANT NOTICE FOR PROSPECTIVE HEARING AID USERS

Good health practice requires that a person with a hearing loss have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists or otorhinolaryngologists. The purpose of medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased.

Following the medical evaluation, the physician will give you a written statement that states that your hearing loss has been medically evaluated and that you may be considered a candidate for a hearing aid. The physician will refer you to an audiologist or a hearing aid dispenser, as appropriate, for a hearing aid evaluation.

The audiologist or hearing aid dispenser will conduct a hearing aid evaluation to assess your ability to hear with and without a hearing aid. The hearing aid evaluation will enable the audiologist or dispenser to select and fit a hearing aid to your individual needs.

If you have reservations about your ability to adapt to amplification, you should inquire about the availability of a trial-rental or purchase-option program. Many hearing aid dispensers now offer programs that permit you to wear a hearing aid for a period of time for a nominal fee after which you may decide if you want to purchase the hearing aid.

Federal law restricts the sale of hearing aids to those individuals who have obtained a medical evaluation from a licensed physician. Federal law permits a fully informed adult to sign a waiver statement declining the medical evaluation for religious or personal beliefs that preclude consultation with a physician. The exercise of such a waiver is not in your best health interest and its use is strongly discouraged.

CHILDREN WITH HEARING LOSS

In addition to seeing a physician for a medical evaluation, a child with a hearing

loss should be directed to an audiologist for evaluation and rehabilitation since hearing loss may cause problems in language development and the educational and social growth of a child. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of a child with a hearing loss.

(4) *Technical data.* Technical data useful in selecting, fitting, and checking the performance of a hearing aid shall be provided in the User Instructional Brochure or in separate labeling that accompanies the device. The determination of technical data values for the hearing aid labeling shall be conducted in accordance with the test procedures of the Acoustical Society of America Standard for Specification of Hearing Aid Characteristics, ASA STD 7-1976.[1] As a minimum, the User Instructional Brochure or such other labeling shall include the appropriate values or information for the following technical data elements as these elements are defined or used in such standard:

(i) Saturation output curve (SSPL 90 curve).
(ii) Frequency response curve.
(iii) Average saturation output (HF-Average SSPL 90).
(iv) Average full-on gain (HF-Average full-on gain).
(v) Reference test gain.
(vi) Frequency range.
(vii) Total harmonic distortion.
(viii) Equivalent input noise.
(ix) Battery current drain.
(x) Induction coil sensitivity (telephone coil aids only).
(xi) Input-output curve (ACG aids only).
(xii) Attack and release times (ACG aids only).

(5) *Statement if hearing aid is used or rebuilt.* If a hearing aid has been used or rebuilt, this fact shall be declared on the container in which the hearing aid is packaged and on a tag that is physically attached to such hearing aid. Such fact may also be stated in the User Instructional Brochure.

(6) *Statements in User Instructional Brochure other than those required.* A User Instructional Brochure may contain statements or illustrations in addition to those required by paragraph (c) of this section if the additional statements:

(i) Are not false or misleading in any particular, e.g., diminishing the impact of the required statements; and

(ii) Are not prohibited by this chapter or by regulations of the Federal Trade Commission.

(d) *Submission of all labeling for each type of hearing aid.* Any manufacturer of a hearing aid described in paragraph (a) of this section shall submit to the Food and Drug Administration, Bureau of Medical Devices and Diagnostic Products, Division of Compliance, HFK-116, 8757 Georgia Ave., Silver Spring, MD 20910, a copy of the User Instructional Brochure described in paragraph (c) of this section and all other labeling for each type of hearing aid on or before August 15, 1977.

[42 FR 9294, Feb. 15, 1977]

§ 801.421 Hearing aid devices; conditions for sale.

(a) *Medical evaluation requirements*—(1) *General.* Except as provided in paragraph (a)(2) of this section, a hearing aid dispenser shall not sell a hearing aid unless the prospective user has presented to the hearing aid dispenser a written statement signed by a licensed physician that states that the patient's hearing loss has been medically evaluated and the patient may be considered a candidate for a hearing aid. The medical evaluation must have taken place within the preceding 6 months.

(2) *Waiver to the medical evaluation requirements.* If the prospective hearing aid user is 18 years of age or older, the hearing aid dispenser may afford the prospective user an opportunity to waive the medical evaluation requirement of paragraph (a)(1) of this section provided that the hearing aid dispenser:

(i) Informs the prospective user that the exercise of the waiver is not in the user's best health interest;

(ii) Does not in any way actively encourage the prospective user to waive such a medical evaluation; and

(iii) Affords the prospective user the opportunity to sign the following statement:

[1] Copies available from the Acoustical Society of America, 335 E. 45th St., New York, N.Y. 10017.

I have been advised by ————————————————(Hearing aid dispenser's name) that the Food and Drug Administration has determined that my best health interest would be served if I had a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. I do not wish a medical evaluation before purchasing a hearing aid.

(b) *Opportunity to review User Instructional Brochure.* Before signing any statement under paragraph (a)(2)(iii) of this section and before the sale of a hearing aid to a prospective user, the hearing aid dispenser shall:

(1) Provide the prospective user a copy of the User Instructional Brochure for a hearing aid that has been, or may be selected for the prospective user;

(2) Review the content of the User Instructional Brochure with the prospective user orally, or in the predominate method of communication used during the sale;

(3) Afford the prospective user an opportunity to read the User Instructional Brochure.

(c) *Availability of User Instructional Brochure.* (1) Upon request by an individual who is considering purchase of a hearing aid, a dispenser shall, with respect to any hearing aid that he dispenses, provide a copy of the User Instructional Brochure for the hearing aid or the name and address of the manufacturer or distributor from whom a User Instructional Brochure for the hearing aid may be obtained.

(2) In addition to assuring that a User Instructional Brochure accompanies each hearing aid, a manufacturer or distributor shall with respect to any hearing aid that he manufactures or distributes:

(i) Provide sufficient copies of the User Instructional Brochure to sellers for distribution to users and prospective users;

(ii) Provide a copy of the User Instructional Brochure to any hearing aid professional, user, or prospective user who requests a copy in writing.

(d) *Recordkeeping.* The dispenser shall retain for 3 years after the dispensing of a hearing aid a copy of any written statement from a physician required under paragraph (a)(1) of this section or any written statement waiving medical evaluation required under paragraph (a)(2)(iii) of this section.

(e) *Exemption for group auditory trainers.* Group auditory trainers, defined as a group amplification system purchased by a qualified school or institution for the purpose of communicating with and educating individuals with hearing impairments, are exempt from the requirements of this section.

[42 FR 9296, Feb. 15, 1977]

NOTE: Incorporation by reference approved by the Director of the Office of the Federal Register on January 13, 1977, and it is on file in the FEDERAL REGISTER library.

§ 801.425 Nonrestricted devices in self-pressurized containers with chlorofluorocarbon propellants.

(a) The label on each package of a nonrestricted device in a self-pressurized container in which the propellant consists in whole or in part of a fully halogenated chlorofluoroalkane (chlorofluorocarbon) shall bear the following warning:

Warning—Contain a chlorofluorocarbon that may harm the public health and environment by reducing ozone in the upper atmosphere.

(b) The warning required by paragraph (a) of this section shall appear on an appropriate panel with such prominence and conspicuousness as to render it likely to be read and understood by ordinary individuals under normal conditions of purchase. The warning may appear on a firmly affixed tag, tape, card, sticker or similar overlabeling attached to the package. The warning shall appear prominent and conspicuously as compared to other words, statements, designs, or devices and in bold type on contrasting background, but in no case may the letter be less than $\frac{1}{16}$ inch in height.

(c) The warning in paragraph (a) of this section is not required and should not be used for products intended for metered-dose adrenergic bronchodilators for oral inhalation, and for cytology fixative uses.

(d) The warning required by paragraph (a) of this section is applicable only to self-pressurized containers that use a chlorofluorocarbon in whole or in part as a propellant to expel from the container liquid or

solid material different from the propellant.

(Secs. 201(n), 301, 402, 403, 501, 502, 505, 507, 512, 601, 602, 52 Stat. 1041-1043 as amended, 1046-1048 as amended, 1049, 1051-1053 as amended, 1054, 57 Stat. 463 as amended, 82 Stat. 343-351 (21 U.S.C. 321(n), 331, 342, 343, 351, 352, 355, 357, 360b, 361, 362); sec. 101(2), 83 Stat. 853 (42 U.S.C. 4332))

[42 FR 22034, Apr. 29, 1977]

§ 801.427 Professional and patient labeling for intrauterine contraceptive devices.

(a) This section applies to intrauterine devices (IUD's) that are not subject to new drug requirements under § 310.502 of this chapter. IUD's subject to this section (device IUD's) include:

(1) IUD's fabricated solely from inactive materials, e.g., inactive plastics or metals.

(2) IUD's with substances added to improve the physical characteristics if such substances do not contribute to contraception through chemical action on or within the body and are not dependent upon being metabolized for the achievement of the contraceptive purpose.

(3) IUD's that contain a component, such as barium, added exclusively for the purpose of visualization by x-ray.

(b) The intrauterine contraceptive device (IUD) is a popular method of contraception used by several million women in the United States. Although this method of contraception is generally safe and effective, certain complications and side effects may result from its use. A Food and Drug Administration review of the labeling of IUD's currently marketed in the United States reveals that information necessary for the safe and effective use of these products is not uniformly available to either the practitioner or the patient. Based on the review of the labeling and on the recommendations of the Ad Hoc Obstetric-Gynecology Advisory Committee, the Commissioner has concluded that in the interest of safe and effective use, and prevention of misleading labeling, there is a need to establish uniform physician and patient labeling for such devices.

(1) Labeling accompanying each IUD and directed to the physician shall be substantially as follows adjusted where appropriate to the requirements of a particular device IUD:

DESCRIPTION

(TO BE SUPPLIED BY MANUFACTURER)

Description shall include the following information:

1. Proprietary or established name of the IUD.
2. Major ingredients or composition.
3. Model.
4. Physical dimensions (size and shape).
5. Description of components in package or system.
6. A statement that the product is sterile.
7. Other characteristics.

MODE OF ACTION OR PRINCIPLES OF IUD DESIGN

(TO BE SUPPLIED BY THE MANUFACTURER)

The manufacturer shall include information on the mode of action or principles of the IUD's design. At a minimum, the statement should provide that IUD's seem to interfere in some manner with nidation in the endometrium, probably through foreign body reaction in the uterus.

INDICATIONS AND USAGE

The labeling may include indications and usages other than those stated below, provided that an approved premarket approval application is in effect. (Name of IUD) is indicated for contraception.

CONTRAINDICATIONS

IUD's should not be inserted when the following conditions exist:

1. Pregnancy or suspicion of pregnancy.
2. Abnormalities of the uterus resulting in distortion of the uterine cavity.
3. Acute pelvic inflammatory disease or a history of repeated pelvic inflammatory disease.
4. Post partum endometritis or infected abortion in the past 3 months.
5. Known or suspected uterine or cervical malignancy including unresolved, abnormal "Pap" smear.
6. Genital bleeding of unknown etiology.
7. Untreated acute cervicitis until infection is controlled.

WARNINGS

1. *Pregnancy*—a. *Long-term effects.* Long-term effects on the offspring when pregnancy occurs with (name of IUD) in place are unknown.

b. *Septic abortion.* Reports have indicated an increased incidence of septic abortion associated in some instances with septicemia, septic shock, and death in patients becoming pregnant with an IUD in place. Most of

these reports have been associated with the mid-trimester of pregnancy. In some cases, the initial symptoms have been insidious and not easily recognized. If pregnancy should occur with an IUD in place, the IUD should be removed if the string is visible or, if removal proves to be or would be difficult, termination of the pregnancy should be considered and offered the patient as an option bearing in mind that the risks associated with an elective abortion increase with gestational age.

c. *Continuation of pregnancy.* If the patient chooses to continue the pregnancy, she must be warned of the increased risk of spontaneous abortion and of the increased risk of sepsis, including death if the pregnancy continues with the IUD in place. The patient must be closely observed and she must be advised to report all abnormal symptoms, such as flu-like syndrome, fever, abdominal cramping and pain, bleeding, or vaginal discharge, immediately because generalized symptoms of septicemia may be insidious.

2. *Ectopic pregnancy.* a. A pregnancy that occurs with an IUD in place is more likely to be ectopic than a pregnancy occurring without an IUD in place. Accordingly, patients who become pregnant while using the IUD should be carefully evaluated for the possibility of an ectopic pregnancy.

b. Special attention should be directed to patients with delayed menses, slight metrorrhagia and/or unilateral pelvic pain and to those patients who wish to terminate a pregnancy because of IUD failure to determine whether ectopic pregnancy has occurred.

3. *Pelvic infection.* Pelvic infection may occur with the IUD in place and at times result in the development of tubo-ovarian abscesses or general peritonitis. Appropriate aerobic and anaerobic bacteriological studies should be done and antibiotic therapy initiated. If the infection does not show a marked clinical improvement within 24 to 48 hours, the IUD should be removed and the continuing treatment reassessed based upon the results of culture and sensitivity tests.

4. *Embedment.* Partial penetration or lodging of the IUD in the endometrium can result in difficult removals.

5. *Perforation.* Partial or total perforation of the uterine wall or cervix may occur with the use of IUD's. The possibility of perforation must be kept in mind during insertion and at the time of any subsequent examination. If perforation occurs, the IUD should be removed. Adhesions, foreign body reactions, and intestinal obstruction may result if an IUD is left in the peritoneal cavity.

PRECAUTIONS

1. *Patient counseling.* Prior to insertion the physician, nurse, or other trained health professional must provide the patient with the Patient Brochure. The patient should be given the opportunity to read the brochure and discuss fully any questions she may have concerning the IUD as well as other methods of contraception.

2. *Patient evaluation and clinical considerations.* a. A complete medical history should be obtained to determine conditions that might influence the selection of an IUD. Physical examination should include a pelvic examination, "Pap" smear, gonorrhea culture and, if indicated, appropriate tests for other forms of venereal disease.

b. The uterus should be carefully sounded prior to insertion to determine the degree of patency of the endocervical canal and the internal os, and the direction and depth of the uterine cavity. In occasional cases, severe cervical stenosis may be encountered. Do not use excessive force to overcome this resistance.

c. The uterus should sound to a depth of 6 to 8 centimeters (cm). Insertion of an IUD into a uterine cavity measuring less than 6.5 cm by sounding may increase the incidence of expulsion, bleeding, and pain.

d. The possibility of insertion in the presence of an existing undetermined pregnancy is reduced if insertion is performed during or shortly following a menstrual period. The IUD should not be inserted post partum or postabortion until involution of the uterus is completed. The incidence of perforation and expulsion is greater if involution is not completed.

e. IUD's should be used with caution in those patients who have anemia or a history of menorrhagia or hypermenorrhea. Patients experiencing menorrhagia and/or metrorrhagia following IUD insertion may be at risk for the development of hypochromic microcytic anemia. Also, IUD's should be used with caution in patients receiving anticoagulants or having a coagulopathy.

f. Syncope, bradycardia, or other neurovascular episodes may occur during insertion or removal of IUD's, especially in patients with a previous disposition to these conditions.

g. Patients with valvular or congenital heart disease are more prone to develop subacute bacterial endocarditis than patients who do not have valvular or congenital heart disease. Use of an IUD in these patients may represent a potential source of septic emboli.

h. Use of an IUD in those patients with acute cervicitis should be postponed until proper treatment has cleared up the infection.

i. Since an IUD may be expelled or displaced, patients should be reexamined and

evaluated shortly after the first postinsertion menses, but definitely within 3 months after insertion. Thereafter annual examination with appropriate medical and laboratory examination should be carried out.

j. The patient should be told that some bleeding and cramps may occur during the first few weeks after insertion, but if these symptoms continue or are severe she should report them to her physician. She should be instructed on how to check after each menstrual period to make certain that the thread still protrudes from the cervix, and she should be cautioned that there is no contraceptive protection if the IUD is expelled. She should be cautioned not to pull on the thread and displace the IUD. If partial expulsion occurs, removal is indicated and a new IUD may be inserted.

k. The use of medical diathermy (shortwave and microwave) in patients with metal-containing IUD's may cause heat injury to the surrounding tissue. Therefore, medical diathermy to the abdominal and sacral areas should not be used.

Adverse Reactions

These adverse reactions are not listed in any order of frequency or severity.

Reported adverse reactions include: endometritis, spontaneous abortion, septic abortion, septicemia, perforation of the uterus and cervix, embedment, fragmentation of the IUD, pelvic infection, vaginitis, leukorrhea, cervical erosion, pregnancy, ectopic pregnancy, difficult removal, complete or partial expultion of the IUD, intermenstrual spotting, prolongation of menstrual flow, anemia, pain and cramping, dysmenorrhea, backaches, dyspareunia, neurovascular episodes including bradycardia and syncope secondary to insertion. Perforation into the abdomen has been followed by abdominal adhesions, intestinal penetration, intestinal obstruction, and cystic masses in the pelvis.

Directions For Use

(TO BE SUPPLIED BY MANUFACTURER)

Directions for use shall include the following:

1. Insertion technique.
2. Requirements for replacement and removal, if applicable.

Clinical Studies

Different event rates have been recorded with the use of different IUD's. Inasmuch as these rates are usually derived from separate studies conducted by different investigators in several population groups, they cannot be compared with precision. Furthermore, event rates tend to be lower as clinical experience is expanded, possibly due to retention in the clinical study of those patients who accept the treatment regimen and do not discontinue due to adverse reactions or pregnancy. In clinical trials conducted by (name of sponsor) with the (name of IUD), use effectiveness was determined as follows for parous and nulliparous women, as tabulated by the life table method. (Rates are expressed as events per 100 women through 12 and 24 months of use.) This experience is based on (number) women/months of use including (number) women who completed 12 months of use and (number) women who completed 24 months of use.

	12 mo		24 mo	
	Parous	Nulliparous	Parous	Nulliparous
Pregnancy				
Expulsion				
Medical removal				
Continuation rate				

(2) Labeling, in sufficient quantities to be available to patients who express interest in IUD's shall accompany each IUD (packaged separately from the sterile packaging), be made available to the patient, and contain the following information:

Patient Information

This brochure provides information on the use of Intrauterine Contraceptive Devices (IUD's). There are other birth control methods that may be suitable. Before deciding which type of birth control method to use, you should read this brochure and have the opportunity to discuss fully with your doctor any questions you may have about the IUD and other methods of contraception.

Preinsertion Information

WHAT YOU SHOULD KNOW ABOUT THE IUD

IUD's are small articles of various sizes and shapes which are inserted into the uterus (womb). The purpose of the IUD is to prevent pregnancy.

How the IUD prevents pregnancy is not completely understood. Several theories have been suggested. IUD's seem to interfere in some manner with the implantation of the fertilized egg in the lining of the uterine cavity. The IUD does not prevent ovulation.

The effectiveness of the IUD is measured by the pregnancy rate of women who use it and the rate of adverse reactions and side effects requiring removal of the IUD.

Use-Effectiveness

Different pregnancy and adverse reaction rates have been reported with the use of different IUD's. Because these rates are usually derived from separate studies conducted by different investigators in several population groups, they cannot be compared with precision.

In Clinical trials with (name of IUD), ——— patients completed ——— cycles or months in use. The incidence of unplanned pregnancies was ——— per 100 woman years or ——— women out of 100 became pregnant in a year while using an IUD. The incidence of adverse reactions requiring medical removal of the IUD is ——— per 100 woman years or ——— women out of 100 discontinued using the IUD for medical reasons.

What You Should Tell Your Doctor

Before you have an IUD inserted, you should tell you doctor if you have ever had, or suspect you have ever had, any of the following conditions which might make the IUD unsuitable as a method of contraception for you:

Abnormalities of the uterus (womb).
Allergy to copper.
Anemia.
Bleeding between periods.
Cancer of the uterus (womb) or cervix.
Fainting attacks.
Heart disease.
Heart murmur.
Heavy menstrual flow.
Infection of the uterus (womb) or cervix.
Pelvic infection (pus in fallopian tubes).
Prior IUD use.
Prior uterine surgery.
Recent abortion or miscarriage.
Recent pregnancy.
Severe menstrual cramps.
Suspected or possible pregnancy.
Suspicious or abnormal "Pap" smear.
Unexplained genital bleeding.
Vaginal discharge or infection.
Venereal disease.

Adverse Reactions

The following adverse reactions and side effects have been reported and may occur after the IUD is inserted:

Anemia.
Backache.
Blood poisoning (septicemia).
Bowel obstruction.
Cervical infection.
Complete or partial expulsion.
Cysts on ovaries and tubes.
Delayed menstruation.
Difficult removal.
Embedment.
Fainting at the time of insertion or removal.
Fragmentation of the IUD.
Intermenstrual spotting.
Internal abdominal adhesions.
Pain and cramps.
Painful intercourse.
Pelvic infection.
Perforation of the uterus (womb) or cervix.
Pregnancy.
Pregnancy outside the uterus (womb) (tubal or ovarian).
Prolonged or heavy menstrual flow.
Septic abortion (infected miscarriage) followed in some cases by blood poisoning (septicemia) which can lead to death.
Spontaneous abortion (miscarriage).
Vaginal discharge and infection.

If you decide on the IUD as your method of birth control, read the following information and instructions carefully. Please keep this brochure so that you may refer to it. If you have any questions, consult your doctor.

Postinsertion Information

DESCRIPTION

(TO BE SUPPLIED BY MANUFACTURER)

Description shall include the following information.

1. Proprietary or established name of the IUD.
2. Model.
3. Physical dimensions (size and shape).
4. Composition (metal or plastic).
5. Color and number of the tail or threads.
6. Other characteristics.

Directions For Use

1. *Checking your IUD.* A tail or thread is attached to the IUD so that you can check to see if it is still in place since the IUD can come out of the uterus (womb) without your knowing it. This occurs most often during or right after a menstrual period.

Follow these steps to make sure your IUD is in place:

a. Wash your hands.

b. Assume the squatting position or seat yourself on the toilet.

c. Insert the index or middle finger high in vagina and locate the cervix (mouth of the uterus (womb)). The cervix feels firm like the tip of your nose.

d. Feel for the tail or thread of the IUD, which should be in the cervix high in your vagina.

e. If you can feel the tail or thread it is likely that the IUD is in place and working. You should not pull on the tail or thread. This may displace the IUD.

f. After each menstrual period, you should check to make sure the tail or thread is in place in the cervix You may check for the tail or thread more often if you wish.

g. If you think the IUD has come out or h as been displaced (i.e., you cannot feel the tail or thread or you can feel the IUD itself), use another birth control method, such as contraceptive vaginal foam, cream, or jelly, or condoms (rubbers), until you can be checked. (These alternative methods are not as effective as IUD's.) Call your doctor for an examination.

h. You should return to see your doctor as soon as possible after your next menstrual period, after insertion of your IUD, but no later than 3 months after insertion. This will allow the doctor to make sure that the IUD is in the correct position.

i. After your first checkup, you should be checked at least once a year by your doctor.

2. *Continuation and removal.* While you are wearing the IUD, you may use tampons and take douches, if this is your usual practice. With some IUD's, you may wear the IUD until you wish to become pregnant. Check with your doctor concerning this. You should return to your doctor if you wish to have the IUD removed.

Side Effects

The following may occur during or after the IUD is inserted:

1. Some bleeding occurs following insertion in most women. Because of this, your doctor may choose to insert your IUD during or at the end of your menstrual period. This also reduces the possibility that you are pregnant at the time of IUD insertion.

2. Bleeding between menstrual periods usually in the form of spotting, may occur during the first 2 or 3 months after insertion. The first few menstrual periods after the insertion may be heavier and longer. If these conditions continue for longer than 2 or 3 months, consult your doctor.

3. Pain, usually in the form of uterine cramps or low backache, may occur at the time of insertion and last for a few days. Simple pain medication usually relieves the cramping.

4. Fainting may occur at the time of insertion or removal of an IUD. This passes quickly and is not usually serious.

5. The IUD may be expelled during the first two or three menstrual cycles following insertion. Expulsion increases the risk of an unplanned pregnancy. Although not as effective as the IUD, the use of a second contraceptive method, such as a contraceptive vaginal foam, cream, or jelly, or condoms (rubbers), is recommended.

Warnings

1. Call your doctor for any of the following reasons:

a. *Severe or prolonged bleeding.* If the flow is heavier and lasts much longer than your usual menstrual flow, you may need to have the IUD removed to prevent the development of anemia.

b. *Pelvic pain and cramps.* This could mean an infection has developed requiring treatment.

c. *Exposure to venereal disease (VD).* If exposure to venereal disease is suspected, report for examination and treatment promptly. Failure to do so could result in serious pelvic infection because use of an IUD in itself does not prevent venereal disease.

d. *Tail or thread disappearance.* If you cannot feel the tail or thread coming through the cervix, it is possible that the IUD has been expelled or displaced or that perforation has occurred. If any of these has occurred you are no longer protected from becoming pregnant. Use another birth control method, such as contraceptive vaginal foam, cream, or jelly, or condoms (rubbers), until you can be checked. (These alternative methods are not as effective as the IUD).

2. Do not undergo medical diathermy (including shortwave or microwave) treatments to the abdomen or lower back areas if you are wearing a metal IUD. these treatments may cause heat injury to the surrounding tissues.

Special Warning About Pregnancy With an IUD in Place

Some women become pregnant while using an IUD. If you miss your menstrual period, or if you have a scanty flow during your period, or if you suspect that you might be pregnant, see your doctor right away. Serious complication of sepsis (severe infection), septic abortion (infected miscarriage), and death have occurred when a pregnancy continues with an IUD in place. Most of the occurrences of these serious complications have been reported in the middle third of pregnancy.

If your doctor confirms that you are pregnant, he should remove the IUD if the tail is visible. Removal of an IUD in pregnancy decreases the likelihood of serious complications.

If removal of your IUD proves to be difficult, you and your doctor shoud discuss at

that time the question of continuing the pregnancy in view of the serious complications that may occur. In reaching a decision as to whether or not to have an abortion, it should be remembered that the risks associated with terminating a pregnancy increase with the length of time you are pregnant.

(3) Any device IUD that is not labeled as required by this section and that is either introduced or delivered for introduction into interstate commerce, or held for sale after shipment in interstate commerce after November 7, 1977 is misbranded pursuant to section 502 of the act. However, an IUD in the possession of an independent wholesaler, a retailer, or a licensed practitioner before November 7, 1977 is not misbranded if labeling required by paragraph (b)(2) of this section is furnished to such independent wholesalers, retailers, or licensed practitioners in sufficient quantities to accompany each device in their possession.

(Secs. 201(g), (h), 502, 505, 520(e), 52 Stat. 1041 as amended, 1050-1053 as amended, 90 Stat. 567 (21 U.S.C. 321(g), (h), 352, 355, 360j(e)))

[42 FR 23780, May 10, 1977; 42 FR 35155, July 8, 1977]

PART 809—IN VITRO DIAGNOSTIC PRODUCTS FOR HUMAN USE

Subpart A—General Provisions

Sec.

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Subpart B—Labeling

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Subpart D—Administrative Procedures

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809.30 Procedure for establishing, amending or repealing standards.
809.34 Court appeal.
809.35 Regulatory action.

AUTHORITY: Sec. 701, 52 Stat. 1055-1056 as amended (21 U.S.C. 371) unless otherwise noted.

SOURCE: 41 FR 6903, Feb. 13, 1976, unless otherwise noted.

Subpart A—General Provisions

§ 809.3 Definitions.

(a) "In vitro diagnostic products" are those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body. These products are devices as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (the act), and may also be biological products subject to section 351 of the Public Health Service Act.

(b) A "product class" is all those products intended for use for a particular determination or for a related group of determinations or products with common or related characteristics or those intended for common or related uses. A class may be further divided into subclasses when appropriate.

(c) [Reserved]

(d) "Act" means the Federal Food, Drug, and Cosmetic Act.

(Secs. 501, 502, 513, 514, 701, 52 Stat. 1049-1051 as amended, 1055-1056 as amended, 90 Stat. 540-552 (21 U.S.C. 351, 352, 360c, 360d, 371))

[41 FR 6903, Feb. 13, 1976, as amended at 45 FR 7484, Feb. 1, 1980]

EFFECTIVE DATE NOTE: At 45 FR 7484, Feb. 1, 1980, paragraph (a) was revised and paragraph (c) was removed. This regulation will become effective July 30, 1980, provided that approval of the reporting and recordkeeping requirements is received from the Office of Management and Budget by that date. For the convenience of the user, the superseded text appears below.

809.3 Definitions.

(a) "In vitro diagnostic products" are those reagents, instruments and systems intended for use in the diagnosis of disease or in the determination of the state of health in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation and examination of specimens taken from the human body. These products are drugs or devices as defined in section 201(g) and 201(h), respectively, of the Federal Food, Drug, and Cosmetic Act (the act) or are a combination of drugs and devices, and may also be a biological product subject to section 351 of the Public Health Service Act.

* * * * *

(c) A "product class standard" is a statement describing performance requirements necessary to assure accuracy and reliability of results, specific labeling requirements necessary for the proper use of a particular class, and procedures for testing the product to assure its satisfactory performance.

* * * * *

§ 809.4 Confidentiality of submitted information.

Data and information submitted under § 809.10(c) that are shown to fall within the exemption established in § 20.61 of this chapter shall be treated as confidential by the Food and Drug Administration and any person to whom the data and information are referred. The Food and Drug Administration will determine whether information submitted will be treated as confidential in accordance with the provisions of Part 20 of this chapter.

(Secs. 501, 502, 513, 514, 701, 52 Stat. 1049-1051 as amended, 1055-1056 as amended, 90 Stat. 540-552 (21 U.S.C. 351, 352, 360c, 360d, 371))

[45 FR 7484, Feb. 1, 1980]

EFFECTIVE DATE NOTE: At 45 FR 7484, Feb. 1, 1980, §809.4 was revised. This regulation will become effective July 30, 1980, provided that approval of the reporting and recordkeeping requirements is received from the Office of Management and Budget by that date. For the convenience of the user, the superseded text appears below.

§ 809.4 Confidentiality of submitted information.

(a) Data and information submitted pursuant to the provisions of § 809.30 or § 809.10(c) and falling within the confiden-

tiality provisions of 18 U.S.C. 1905 or 21 U.S.C. 331(j) shall be treated as confidential by the Food and Drug Administration and any consultant to whom it is referred. Confidentiality of information will be determined in accordance with the provisions of Part 20 of this chapter.

(b) Data and information submitted pursuant to § 809.30 in connection with the establishment, amendment or repeal of a product class standard will be made publicly available at the office of the Hearing Clerk of the Food and Drug Administration 30 days after publication of a proposed product class standard, except for the identity of inactive ingredients, any quality control or other manufacturing data or information, or other data and information to the extent that the person submitting it has demonstrated that it falls within the confidentiality provisions of 18 U.S.C. 1905 or 21 U.S.C. 331(j).

[41 FR 6903, Feb. 13, 1976, as amended at 42 FR 15676, Mar. 22, 1977]

Subpart B—Labeling

§ 809.10 Labeling for in vitro diagnostic products.

(a) The label for an in vitro diagnostic product shall state the following information, except where such information is not applicable, or as otherwise specified in a standard for a particular product class. Section 201(k) of the act provides that "a requirement made by or under authority of this act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper."

(1) The proprietary name and established name (common or usual name), if any.

(2) The intended use or uses of the product.

(3) For a reagent, a declaration of the established name (common or usual name), if any, and quantity, proportion or concentration of each reactive ingredient; and for a reagent derived from biological material, the source and a measure of its activity. The quantity, proportion, concentration, or activity shall be stated in the system generally used and recognized by the intended user, e.g., metric, international units, etc.

(4) A statement of warnings or precautions for users as established in the regulations contained in 16 CFR Part 1500 and any other warnings appropriate to the hazard presented by the product; and a statement "For In Vitro Diagnostic Use" and any other limiting statements appropriate to the intended use of the product.

(5) For a reagent, appropriate storage instructions adequate to protect the stability of the product. When applicable, these instructions shall include such information as conditions of temperature, light, humidity, and other pertinent factors. For products requiring manipulation, such as reconstitution and/or mixing before use, appropriate storage instructions shall be provided for the reconstituted or mixed product which is to be stored in the original container. The basis for such instructions shall be determined by reliable, meaningful, and specific test methods such as those described in § 211.60 of this chapter.

(6) For a reagent, a means by which the user may be assured that the product meets appropriate standards of identity, strength, quality and purity at the time of use. This shall be provided, both for the product as provided and for any resultant reconstituted or mixed product, by including on the label one or more of the following:

(i) An expiration date based upon the stated storage instructions.

(ii) A statement of an observable indication of an alteration of the product, e.g., turbidity, color change, precipitate, beyond its appropriate standards.

(iii) Instructions for a simple method by which the user can reasonably determine that the product meets its appropriate standards.

(7) For a reagent, a declaration of the net quantity of contents, expressed in terms of weight or volume, numerical count, or any combination of these or other terms which accurately reflect the contents of the package. The use of metric designations is encouraged, wherever appropriate. If more than a single determination may be performed using the product, any

statement of the number of tests shall be consistent with instructions for use and amount of material provided.

(8) Name and place of business of manufacturer, packer, or distributor.

(9) A lot or control number, identified as such, from which it is possible to determine the complete manufacturing history of the product.

(i) If it is a multiple unit product, the lot or control number shall permit tracing the identity of the individual units.

(ii) For an instrument, the lot or control number shall permit tracing the identity of all functional subassemblies.

(iii) For multiple unit products which require the use of included units together as a system, all units should bear the same lot or control number, if appropriate, or other suitable uniform identification should be used.

(10) Except that for items in paragraph (a) (1) through (9) of this section: (i) In the case of immediate containers too small or otherwise unable to accommodate a label with sufficient space to bear all such information and which are packaged within an outer container from which they are removed for use, the information required by paragraph (a) (2), (3), (4), (5), (6) (ii), (iii) and (7) of this section may appear in the outer container labeling only.

(ii) In any case in which the presence of this information on the immediate container will interfere with the test, the information may appear on the outside container or wrapper rather than on the immediate container label.

(b) Labeling accompanying each product, e.g., a package insert, shall state in one place the following information in the format and order specified below, except where such information is not applicable, or as specified in a standard for a particular product class. The labeling for a multiple-purpose instrument used for diagnostic purposes, and not committed to specific diagnostic procedures or systems, may bear only the information indicated in paragraph (b) (1), (2), (6), (14), and (15) of this section. The labeling for a reagent intended for use as a replacement in a diagnostic system may be limited to that information necessary to identify the reagent adequately and to describe its proper use in the system.

(1) The proprietary name and established name, i.e., common or usual name, if any.

(2) The intended use or uses of the product and the type of procedure, e.g., qualitative or quantitative.

(3) Summary and explanation of the test. Include a short history of the methodology, with pertinent references and a balanced statement of the special merits and limitations of this method or product. If the product labeling refers to any other procedure, appropriate literature citations shall be included and the labeling shall explain the nature of any differences from the original and their effect on the results.

(4) The chemical, physical, physiological, or biological principles of the procedure. Explain concisely, with chemical reactions and techniques involved, if applicable.

(5) Reagents: (i) A declaration of the established name (common or usual name), if any, and quantity, proportion or concentration or each reactive ingredient; and for biological material, the source and a measure of its activity. The quantity, proportion, concentration or activity shall be stated in the system generally used and recognized by the intended user, e.g., metric, international units, etc. A statement indicating the presence of and characterizing any catalytic or nonreactive ingredients, e.g., buffers, preservatives, stabilizers.

(ii) A statement of warnings or precautions for users as established in the regulations contained in 16 CFR Part 1500 and any other warnings appropriate to the hazard presented by the product; and a statement "For In Vitro Diagnostic Use" and any other limiting statements appropriate to the intended use of the product.

(iii) Adequate instructions for reconstitution, mixing, dilution, etc.

(iv) Appropriate storage instructions adequate to protect the stability of the product. When applicable, these instructions shall include such information as conditions of temperature,

light, humidity, and other pertinent factors. For products requiring manipulation, such as reconstitution and/or mixing before use, appropriate storage instructions shall be provided for the reconstituted or mixed product. The basis for such instructions shall be determined by reliable, meaningful, and specific test methods such as those described in § 211.60 of this chapter.

(v) A statement of any purification or treatment required for use.

(vi) Physical, biological, or chemical indications of instability or deterioration.

(6) Instruments: (i) Use or function.

(ii) Installation procedures and special requirements.

(iii) Principles of operation.

(iv) Performance characteristics and specifications.

(v) Operating instructions.

(vi) Calibration procedures including materials and/or equipment to be used.

(vii) Operational precautions and limitations.

(viii) Hazards.

(ix) Service and maintenance information.

(7) Specimen collection and preparation for analysis, including a description of: (i) Special precautions regarding specimen collection including special preparation of the patient as it bears on the validity of the test.

(ii) Additives, preservatives, etc., necessary to maintain the integrity of the specimen.

(iii) Known interfering substances.

(iv) Recommended storage, handling or shipping instructions for the protection and maintenance of stability of the specimen.

(8) Procedure: A step-by-step outline of recommended procedures from reception of the specimen to obtaining results. List any points that may be useful in improving precision and accuracy. (i) A list of all materials provided, e.g., reagents, instruments and equipment, with instructions for their use.

(ii) A list of all materials required but not provided. Include such details as sizes, numbers, types, and quality.

(iii) A description of the amounts of reagents necessary, times required for specific steps, proper temperatures, wavelengths, etc.

(iv) A statement describing the stability of the final reaction material to be measured and the time within which it shall be measured to assure accurate results.

(v) Details of calibration: Identify reference material. Describe preparation of reference sample(s), use of blanks, preparation of the standard curve, etc. The description of the range of calibration should include the highest and the lowest values measurable by the procedure.

(vi) Details of kinds of quality control procedures and materials required. If there is need for both positive and negative controls, this should be stated. State what are considered satisfactory limits of performance.

(9) Results: Explain the procedure for calculating the value of the unknown. Give an explanation for each component of the formula used for the calculation of the unknown. Include a sample calculation, step-by-step, explaining the answer. The values shall be expressed to the appropriate number of significant figures. If the test provides other than quantitative results, provide an adequate description of expected results.

(10) Limitation of the procedure: Include a statement of limitations of the procedure. State known extrinsic factors or interfering substances affecting results. If further testing, either more specific or more sensitive, is indicated in all cases where certain results are obtained, the need for the additional test shall be stated.

(11) Expected values: State the range(s) of expected values as obtained with the product from studies of various populations. Indicate how the range(s) was established and identify the population(s) on which it was established.

(12) Specific performance characteristics: Include, as appropriate, information describing such things as accuracy, precision, specificity, and sensitivity. These shall be related to a generally accepted method using biological specimens from normal and abnormal populations. Include a statement summarizing the data upon which the

specific performance characteristics are based.

(13) Bibliography: Include pertinent references keyed to the text.

(14) Name and place of business of manufacturer, packer, or distributor.

(15) Date of issuance of the last revision of the labeling identified as such.

(c) A shipment or other delivery of an in vitro diagnostic product shall be exempt from the requirements of paragraphs (a) and (b) of this section and from a standard promulgated under Part 861 provided that the following conditions are met:

(1) In the case of a shipment or delivery for an investigation subject to Part 812, if there has been compliance with Part 812; or

(2) In the case of a shipment or delivery for an investigation that is not subject to Part 812 (see § 812.2(c)), if the following conditions are met:

(i) For a product in the laboratory research phase of development, and not represented as an effective in vitro diagnostic product, all labeling bears the statement, prominently placed: "For Research Use Only. Not for use in diagnostic procedures."

(ii) For a product being shipped or delivered for product testing prior to full commercial marketing (for example, for use on specimens derived from humans to compare the usefulness of the product with other products or procedures which are in current use or recognized as useful), all labeling bears the statement, prominently placed: "For Investigational Use Only. The performance characteristics of this product have not been established."

(iii) The person making a shipment or delivery under paragraph (c)(2)(ii) of this section shall submit to FDA at the address in § 812.19 a notification that such shipments are being made.

(d) The labeling of general purpose laboratory reagents (e.g., hydrochloric acid) and equipment (e.g., test tubes and pipettes) whose uses are generally known by persons trained in their use need not bear the directions for use required by § 809.10 (a) and (b), if their labeling meets the requirements of this paragraph.

(1) The label of a reagent shall bear the following information:

(i) The proprietary name and established name (common or usual name), if any, of the reagent.

(ii) A declaration of the established name (common or usual name), if any, and quantity, proportion or concentration of the reagent ingredient (e.g., hydrochloric acid: Formula weight 36.46, assay 37.9 percent, specific gravity 1.192 at 60° F); and for a reagent derived from biological material, the source and where applicable a measure of its activity. The quantity, proportion, concentration or activity shall be stated in the system generally used and recognized by the intended user, e.g., metric, international units, etc.

(iii) A statement of the purity and quality of the reagent, including a quantitative declaration of any impurities present. The requirement for this information may be met by a statement of conformity with a generally recognized and generally available standard which contains the same information, e.g., those established by the American Chemical Society, U.S. Pharmacopeia, National Formulary, National Research Council.

(iv) A statement of warnings or precautions for users as established in the regulations contained in 16 CFR Part 1500 and any other warnings appropriate to the hazard presented by the product; and a statement "For Laboratory Use."

(v) Appropriate storage instructions adequate to protect the stability of the product. When applicable, these instructions shall include such information as conditions of temperature, light, humidity, and other pertinent factors. The basis for such information shall be determined by reliable, meaningful, and specific test methods such as those described in § 211.60 of this chapter.

(vi) A declaration of the net quantity of contents, expressed in terms of weight or volume, numerical count, or any combination of these or other terms which accurately reflect the contents of the package. The use of metric designations is encouraged, wherever appropriate.

(vii) Name and place of business of manufacturer, packer, or distributor.

(viii) A lot or control number, identified as such, from which it is possible

to determine the complete manufacturing history of the product.

(ix) In the case of immediate containers too small or otherwise unable to accommodate a label with sufficient space to bear all such information, and which are packaged within an outer container from which they are removed for use, the information required by paragraph (d)(1)(ii), (iii), (iv), (v), and (vi) of this section may appear in the outer container labeling only.

(2) The label of general purpose laboratory equipment, e.g., a beaker or a pipette, shall bear a statement adequately describing the product, its composition, and physical characteristics if necessary for its proper use.

(Secs. 301, 501, 502, 520, 701(a), 702, 704, 801, 52 Stat. 1042-1043 as amended, 1049-1051 as amended, 1055, 1056-1058 as amended, 67 Stat. 476-477 as amended, 90 Stat. 565-574, (21 U.S.C. 331, 351, 352, 360, 371(a), 372, 374, 381); secs. 501, 502, 513, 514, 701, 52 Stat. 1049-1051 as amended, 1055-1056 as amended, 90 Stat. 540-552 (21 U.S.C. 351, 352, 360c, 360d, 371))

[41 FR 6903, Feb.13, 1976, as amended at 45 FR 3750, Jan. 18, 1980; 45 FR 7484, Feb. 1, 1980]

EFFECTIVE DATE NOTE: 1. The effective date for paragraphs (a) and (b) of this section (formerly § 328.10), as applied to licensed blood grouping serum, was stayed. See 39 FR 2089, Jan. 17, 1974.

2. At 45 FR 3750, Jan. 18, 1980, paragraph (c) of §809.10 was revised. This regulation will become effective July 16, 1980, provided that approval of the reporting and recordkeeping requirements is received from the Office of Management and Budget by that date. For the convenience of the user, the superseded text appears below.

§ 809.10 Labeling for in vitro diagnostic products.

* * * * *

(c) A shipment or other delivery of an in vitro diagnostic product shall be exempt from the requirements of paragraphs (a) and (b) of this section and from a standard promulgated pursuant to this part provided the following conditions are met:

(1) For a product in the laboratory research phase of development, and not represented as an effective in vitro diagnostic product, all labeling bears the statement, prominently placed: "For Research Use Only. Not for use in diagnostic procedures."

(2) For a product being shipped or delivered for product testing prior to full commercial marketing (e.g., for use on specimens derived from humans to compare the usefulness of the product with other products or procedures which are in current use or recognized as useful), all labeling bears the statement, prominently placed: "For Investigational Use Only. The performance characteristics of this product have not been established."

(3) The person making a shipment or delivery under paragraph (c)(2) of this section shall submit to the FDA a notification that such shipments are being made.

(4) Within 30 days after the first commercial shipment of an in vitro diagnostic product, the person making such shipment shall submit the information required by the Drug Listing Act as provided in § 207.25 of this chapter.

* * * * *

3. At 45 FR 7484, Feb. 1, 1980, the introductory text of paragraph (c), which was published at 45 FR 3750, Jan. 18, 1980, was revised. This regulation will become effective July 30, 1980, provided that approval of the reporting and recordkeeping requirements is received from the Office of Management and Budget by that date. For the convenience of the user, the superseded text, originally published at 45 FR 3750, Jan. 18, 1980, appears below.

* * * * *

(c) A shipment or other delivery of an in vitro diagnostic product shall be exempt from the requirements of paragraphs (a) and (b) of this section and from a standard promulgated under Part 861 of this chapter:

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Subpart C—Requirements for Manufacturers and Producers

§ 809.20 General requirements for manufacturers and producers of in vitro diagnostic products.

(a) [Reserved]

(b) *Compliance with good manufacturing practices.* In vitro diagnostic products shall be manufactured in accordance with the good manufacturing practices requirements found in Part 820 of this chapter.

(Secs. 501, 502, 518, 519, 520(f), and 701(a) as amended, 52 Stat. 1049-1051 as amended, 1055, 90 Stat. 562-569 (21 U.S.C. 351, 352, 360h, 360i, 360j(f), 371(a)))

[41 FR 6903, Feb. 13, 1976, as amended at 42 FR 42530, Aug. 23, 1977; 43 FR 31527, July 21, 1978]

Subpart D—Administrative Procedures

EFFECTIVE DATE NOTE: At 45 FR 7484, Feb. 1, 1980, §§ 809.30, 809.34 and 809.35 (Subpart D) were removed. This regulation will become effective July 30, 1980, provided that approval of the reporting and recordkeeping requirements is received from the Office of Management and Budget by that date.

§ 809.30 Procedure for establishing, amending or repealing standards.

(a) *Basis for standards and available approaches to developing standards.* Whenever in the judgment of the Commissioner the establishment of a product class standard is necessary to reduce or eliminate unreasonable risk of illness or injury associated with exposure to or use of an in vitro diagnostic product and there are no other more practicable means to protect the public from such risk, he may propose such a standard. In proposing a product class standard he shall consider, and publish in the FEDERAL REGISTER findings on, the degree of risk or injury associated with the use of the product, the availability of information relating to the sciences upon which the products or their uses are based, the approximate number of products subject to the standard, the medical need for the products, and the probable effect of the standard upon the utility, cost, or availability of the product, and available means of achieving the objective of the standard with a minimal disruption of supply and of reasonable manufacturing and other commercial practices. Three procedures are available for developing product class standards and may be proposed on the initiative of the Commissioner or by petition of interested persons, pursuant to Part 10 of this chapter: (1) An existing standard may be utilized, (2) interested persons outside of the Food and Drug Administration may develop a proposed standard or (3) the Food and Drug Administration may develop the standard.

(b) *Advisory committee.* An advisory committee of qualified experts shall be appointed to advise the Food and Drug Administration on the priorities for establishing product class standards, the scientific basis for in vitro diagnostic products, the selection of reference methodologies and reference materials, the adequacy and reasonableness of proposed standards and other related matters as determined by the Commissioner.

(c) *Request for information and comment.* Whenever a new standard is to be developed, the Commissioner will publish a notice in the FEDERAL REGISTER requesting the submission of all information, data, and views relevant to a specific product class for review and evaluation. Any interested person may submit comments and views on any matter relevant to the development of the standard, including the factors required by paragraph (a) of this section, to be considered by the Commissioner. The format for such submission may be determined by the nature of the information to be submitted. Any product performance information submitted shall relate to the performance of that product as marketed or intended for marketing. For information submitted by a manufacturer of a product which will be affected by the standard, the specific product information requested and the format for submission shall be as described below unless changed in the FEDERAL REGISTER notice. The time allotted for submission will ordinarily be 90 days. Four copies of the information and data on any product within the designated class shall be submitted, indexed, and bound.

(1) Name of product class and date of FEDERAL REGISTER statement.

(2) Proprietary name of product.

(3) Name of person responsible for submission.

(4) Intended use or uses of the product.

(5) A statement categorizing the procedure, e.g., qualitative or quantitative.

(6) Copies of label and all other labeling under which product is currently marketed or, for a proposed product, the label and all other labeling under which marketing is intended.

(7) Description of the product, as appropriate: For example, if the product is or includes a reagent, state the proprietary name and established name,

common or usual name, if any, and quantity, proportion, or concentration of each reactive, catalytic, or inactive ingredient. If the product is a biological material, list the source and a measure of its activity. Include a statement of any purification or treatment required for use. If the product is or includes an instrument or equipment, describe as appropriate its use or functions, installation procedures and any special requirements, principle of operating instructions, calibration procedures including materials and/or equipment to be used, operation precautions and limitations, hazards, and service and maintenance instructions.

(8) Stability information: A description of, and data derived from, studies of the stability of the product. For any product that requires manipulation (e.g., reconstitution or mixing), stability data shall be described for the reconstituted or mixed product. Describe the means by which the information was developed. The data shall be for the product in the container in which it is marketed to assure, among other things, that the container is not reactive, additive, or absorptive to an extent that alters the product or its performance. Include any expiration period data which supports any expiration date which appears in the labeling of the product. Describe the storage conditions necessary for the product, such as temperature, light, humidity.

(9) Hazards to user: A statement of the principal hazards associated with the product. Include the result of tests conducted to determine the applicability of hazard warnings or cautions, including those established in the regulations contained in 16 CFR Part 1500.

(10) History of methodology: A brief history of the methodology, with pertinent references. All references to reports of adverse or unfavorable experience with the product or the procedure on which it is based shall be included. If the product procedure is the same as one which has been published, cite the reference. If the product is based on a modification of a published procedure, cite the reference, state the reason for and the nature of the modification and the effect such modification may have on the results of the procedure as compared to the original. Include data illustrating the comparison of the modified procedure to the original procedure.

(11) Principle of test: An explanation of the test procedure including the chemical, physical, physiological, or biological principle of the procedure with chemical reactions and techniques involved, if applicable.

(12) Specimen collection and preparation: A description of the specimen to be subjected to analysis: (i) Special precautions regarding specimen collections, including special preparation of the patient as it bears on the validity of the test.

(ii) Additives, preservatives, etc., necessary to maintain the integrity of the specimen.

(iii) Known interfering substances and their effect on the procedure and results.

(iv) Appropriate storage, handling or shipping instructions.

(13) Procedure: A detailed, step-by-step description of the test procedure from reception of the specimen to obtaining of results, including any points that may be useful in improving precision and accuracy. Give the exact details of calibration. Identify reference material. Describe preparation of reference sample, use of blanks, etc. Include a description of methods to be used in determining the standard curve.

(14) Results: Explain the procedure for calculating the value of the unknown. Give an explanation of each component of the formula used for the calculation of the unknown. Include a sample calculation, step-by-step, explaining the answer. Values should be expressed to the appropriate number of significant figures. Provide the basis for evaluation of nonquantitative test results.

(15) Limitation of the procedure: Include a statement of the limitations of the procedure and an explanation of extrinsic factors, if any, that may affect the results. Include statements regarding minimum training needed by the user, special precautions, interfering substances, likelihood of obtaining false positive or false negative results, etc. Position data showing a lack of interference by commonly occur-

ring substances shall be supplied. If a more specific or more sensitive laboratory test is indicated in certain instances, the indication for the additional test shall be stated and data submitted to support its value.

(16) Support of claims: Include all available data, published or unpublished, which supports or is critical of the product or its procedure. Include data for both normal and abnormal subjects and a description of the population or populations studies. State, for each claim:

(i) Labeling claim.

(ii) Background documentation: Provide a bibliography and reprints of all pertinent references.

(iii) Procedure used for collecting evidence for claim.

(iv) Description of statistical protocol.

(v) Description of sampling procedure.

(vi) Summary of raw results in tabular form.

(vii) Analysis of results.

(viii) Statement of interpretation of results.

(17) Summary of scientific basis of procedure: A summary of the data and views setting forth the scientific rationale and purpose of the product, and the scientific basis for the conclusion that the product has or has not been proven accurate and reliable for its intended uses. If there is an absence of controlled studies in the material submitted, an explanation as to why such studies are not considered necessary shall be included.

(18) If the submission is by a manufacturer, a statement signed by the person responsible for such submission, that to the best of his knowledge it includes unfavorable information as well as any favorable information, known to him pertinent to an evaluation of the performance of the product. Thus, if any type of scientific data is submitted, a balanced submission of favorable and unfavorable data must be submitted. The same would be true of any other pertinent data or information submitted, such as consumer surveys or marketing results.

(d) *Review and evaluation.* Any existing standard or petition for a product class standard, together with any information and comments submitted pursuant to a published notice, will be reviewed and evaluated by the Food and Drug Administration in consultation with its advisory committee and the Center for Disease Control.

(e) *Proposed product class standard.* When the Commissioner has concluded that the criteria in paragraph (a) of this section are met and the information available has been reviewed and found to justify the establishment of a product class standard, he shall publish in the FEDERAL REGISTER a proposed product class standard establishing conditions under which the products in the class are safe and effective and not adulterated or misbranded. The standard shall include a statement of the performance requirements necessary to assure accuracy and reliability of results, specific labeling requirements for the proper use of the products in the class, and procedures for testing the products to assure satisfactory performance at the time of marketing. The standard may include, where necessary to assure the accuracy and reliability of results, individual lot testing by or at the direction of the Food and Drug Administration, in addition to that normally required of the manufacturer; except that the Commissioner shall exempt any particular product from such a requirement upon a showing that the manufacturer has demonstrated such consistency in the production of that product, in compliance with the regulations, as is adequate to insure the accuracy and reliability of results, and the Commissioner shall revoke the requirement of individual lot testing under the standard when it is no longer necessary to the accuracy and reliability of the results of the product class covered by the standard. Any interested person may, within 60 days after publication of the proposed standard in the FEDERAL REGISTER, file written comments on the proposal, in quintuplicate, with the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857. Comments may be accompanied by a memorandum or brief in support thereof. All comments may be reviewed at the office of the Hearing

Clerk during regular working hours, Monday through Friday.

(f) *Referral to an independent advisory committee.* The Commissioner may, in his discretion, refer a proposal under paragraph (e) of this section to an independent advisory committee of experts qualified in the subject matter at issue, for a report and recommendations with respect to any matter involved in such proposal which involves the exercise of scientific judgment. The Commissioner shall designate the chairman of each panel. The independent advisory committee may consult any person in connection with the matter referred to it. Any interested person may request, in writing, an opportunity to present oral views to the committee. Any interested person may present written data and views which shall be considered by the committee. The full report(s) of the committee and summary minutes of its meetings shall be made available upon request after submission of the report(s) to the Commissioner.

(g) *Final product class standard.* After reviewing all comments received in response to the proposal and considering all available relevant information, the Food and Drug Administration, in consultation with its advisory committee and the Center for Disease Control, and after consideration of any report of an independent advisory committee if the matter involved has been so referred, will publish in the FEDERAL REGISTER a final order containing a product class standard. This order shall state the reasons for promulgating the product class standard and the date the standard will become effective.

(h) *Petition to amend or repeal standards.* The Commissioner may propose to amend or repeal any standard established pursuant to this procedure or any interested person may petition the Commissioner for such action. A petition shall set forth the action requested and a detailed statement in support of the action. After review of the petition, the Commissioner may deny the petition if he finds a lack of reasonable support or he may publish a proposed amendment of or proposed repeal of the established standard in the FEDERAL REGISTER if adequate support has been presented. The petition shall be in the form specified in § 2.65 of this chapter with the number of copies and other information as specified therein. A new drug application submitted for an in vitro diagnostic product which does not comply with an applicable effective product class standard will be considered as a petition to amend the standard. Petitions for repeal or amendment for which reasonable support has been furnished will be handled pursuant to the procedures established in paragraphs (e) through (g) of this section.

[41 FR 6903, Feb. 13, 1976, as amended at 42 FR 4719, Jan. 25, 1977; 42 FR 15676, Mar. 22, 1977]

§ 809.34 Court appeal.

The product class standard promulgated in the final order represents final agency action from which appeal lies to the courts. The Food and Drug Administration will request consolidation of all appeals in a single court. Upon court appeal, the Commissioner, at his discretion, may stay the effective date for part or all of the standard pending appeal and final court adjudication, and may establish a new effective date after final court adjudication.

§ 809.35 Regulatory action.

Any in vitro diagnostic product is subject to regulatory action if it fails to conform to an applicable product class standard or the general labeling requirements of § 809.10. If the product is a device, it is adulterated in violation of section 501 and it is misbranded in violation of section 502 of the act. If the product is a drug, it is in violation of section 505 as well as sections 501 and 502 of the act. If the product is a biologic, it is in violation of sections 501, 502, and 505 of the Federal Food, Drug, and Cosmetic Act and section 351 of the Public Health Service Act. Deviations from an established standard may be justified only by an amendment to the standard. Compliance with this part shall be deemed to constitute compliance with the labeling and new drug requirements of the act and with the labeling and licensing requirements of section 351 of the Public Health Service Act, unless the Commissioner otherwise informs the manufacturer or distributor of an in vitro diagnostic product of additional requirements imposed pursuant to either statute in order to protect the public health.

NOTE: Material incorporated by reference approved by the Director, Office of the Federal Register, February 5, 1976, and on file in the Federal Register library.

FDA 84-4170	Prosthetic Heart Valves: A Study of In Vitro Performance, Phase II Final Report Part I (PB 84-162379, $8.50).
FDA 84-4171	Prosthetic Heart Valves: A Study of In Vitro Performance, Phase II Final Report Part II (PB 84-162387, $10.00).
FDA 84-4172	Prosthetic Heart Valves: A Study of In Vitro Performance, Phase II Final Report Part III (PB 84-162395, $22.00).
FDA 84-4173	Everything You Always Wanted to Know About the Medical Device Amendments and Weren't Afraid to Ask (GPO 017-012-00317-6, $2.00).
FDA 84-4174	Sterile Medical Devices - A GMP Workshop Manual, Fourth Edition (GPO 017-012-00318-4, $12.00) (PB 84-188713, $34.00).
FDA 84-4175	A Study of the Common Characteristics, Hazards, and Performance Problems of Endoscopes and Endoscopic Accessories (PB 84-187202, $26.50).
FDA 84-4176	Evaluation of Automated Differential Cell Counting Devices - Volume I: Review of Literature and Labeling (PB 84-189356, $13.00).
FDA 84-4177	Development of Test Methods and Draft Standard for Cardiac Monitors (PB 84-187756, $13.00).
FDA 84-4178	Standard for Cardiac Monitors, Heart Rate Meters, and Alarms (PB 84-188812, $10.00).
FDA 84-4180	A Study of DC Defibrillator Safety and Performance - Performance and Safety Standard - Volume II (PB 84-188838, $8.50).
FDA 84-4182	Development of Test Methods for Disposable ECG Electrodes - Volume I (PB 84-193960, $14.50).
FDA 84-4184	Safety and Performance of Angiographic and Lymphographic Injectors (PB 84-195544, $13.00).
FDA 84-4185	Safety and Performance of Resuscitators (PB 84-195635, $13.00).
FDA 84-4186	Investigation and Studies on Electrosurgery (PB 84-191634, $14.50).
FDA 84-4187	Safety and Performance of Ventilators (PB 84-188721, $19.00).
FDA 84-4188	Need Help with Medical Device Regs? (pamphlet).
FDA 84-4189	Hypodermic Thermocouple Tissue Cryometers (PB 84-190776, $7.00).
FDA 84-4190	An Investigation of Cerebrospinal Fluid Shunt Valves - Test Results for Twenty-Five Valves: Final Report - Phase III (PB 84-207042, $19.00).
FDA 84-4191	Medical Device GMP Guidance for FDA Investigators.
FDA 84-4192	Problem Definition Study on Liquid Crystal Forehead Temperature Strips (PB 84-187483, $13.00).
FDA 85-4160	Import/Export - Regulatory Requirements for Medical Devices (GPO 017-012-00325-7, $2.25) (supersedes FDA 83-4160) (PB 86-102480, $11.95).
FDA 85-4165	Regulatory Requirements for Medical Devices -A Workshop Manual (supersedes FDA 83-4165) (GPO 017-012-00315-0, $8.50, 435 pp) .
FDA 85-4169	Toxic Shock and Tampons (pamphlet).
FDA 85-4179	Device Good Manufacturing Practices - Third Edition (GPO 017-012-00322-2, $11.00) (PB 85-149334/AS, $31.00).
FDA 85-4192	Toxic Shock Syndrome (poster).
FDA 85-4193	BMD Standards Survey 1982 - International Edition (PB 85-171155/AS, $31.00).
FDA 85-4194	An Overview of the Medical Device Reporting Regulation (PB 86-109709/AS, $9.95).
FDA 85-4195	Surface Cracking of Polyurethane Tubing Resulting from Subcutaneous Implantation in Dogs (PB 85-171619/AS, $10.00).
FDA 85-4196	Medical Device Problem Reporting and the Health Care Professional.
FDA 85-4199	Medical Device Establishment Registration: Information and Instructions (PB 86-123726/AS, $9.95, 8 pp).
FDA 86-4201	Problem Definition Study: Rubella Antibody Testing (PB 86-131935/AS, $9.95, 40 pp).

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Food and Drug Administration
Center for Devices and Radiological Health
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